

The TEMPO Trial at 5 Years: Transoral Fundoplication (TIF 2.0) Is Safe, Durable, and Cost-Effective



BACKGROUND

Questions remain about the therapeutic durability of transoral incisionless fundoplication (TIF). In this study, clinical outcomes were evaluated at 5 years post-TIF 2.0.

METHODS

A total of 63 chronic gastroesophageal reflux disease (GERD) sufferers with troublesome symptoms refractory to proton pump inhibitor (PPI) therapy, absent or ≤ 2 cm hiatal hernia, and abnormal esophageal acid exposure were randomized to the TIF group or PPI group. Following the 6-month evaluation, all patients in the PPI group elected for crossover to TIF; therefore, all 63 patients underwent TIF 2.0 with EsophyX2 device. Primary outcome was elimination of daily troublesome regurgitation and atypical symptoms at the 5-year follow-up. Secondary outcomes were improvement in symptom scores, PPI use, reoperations, and patient health satisfaction. The cost-effectiveness of TIF 2.0 was also estimated.

RESULTS

Of 63 patients, 60 were available at 1 year, 52 at 3 years, and 44 at 5 years for evaluation. Troublesome regurgitation was eliminated in 88% of patients at 1 year, 90% at 3 years, and 86% at 5 years. Resolution of troublesome atypical symptoms was achieved in 82% of patients at 1 year, 88% at 3 years, and 80% at 5 years. No serious adverse events occurred. At the 5-year follow-up, 66% of patients were off daily PPIs and the total GERD health-related quality-of-life score improved by decreasing from 22.2 to 6.8 at 5 years ($P < .001$).

CONCLUSION

In this patient population, the TIF 2.0 procedure provided safe and sustained long-term elimination of troublesome GERD symptoms.

KEY POINTS

1. There were no SAE's or any safety concerns associated with the TIF 2.0 procedure.
2. Troublesome regurgitation was eliminated in 86% of patients at 5 years.
3. Resolution of troublesome atypical symptoms was achieved in 80% of patients at 5 years.
4. Unlike traditional laparoscopic Nissen fundoplication TIF patients did not experience common anti reflux surgery side effects such as gas bloat or dysphagia.
 - Reference JLS 2006 JAN-MAR 10(1) 39-42 for Nissen side effects and Bell 2 year registry for zero TIF de novo side effects.
5. The total GERD Health-related quality-of-life score improved by decreasing from 22.2 to 6.8 at 5 years ($P < .001$).
6. 63 patients met the study inclusion criteria – target randomization (2:1): 40 patients into the TIF group, 23 patients into the PPI group. 70% (44/63) completed the 5-yr follow up assessments.
7. At 6 months evaluation, all patients in randomized PPI group elected to crossover to TIF.
8. Only 34% of patients were still on their index daily PPIs compared to 100% at the beginning of the study.
9. According to optimum data TIF had a 27% or \$27,564 lower cost of care over the 5 year period.

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Learn more about the TIF® Procedure for Reflux

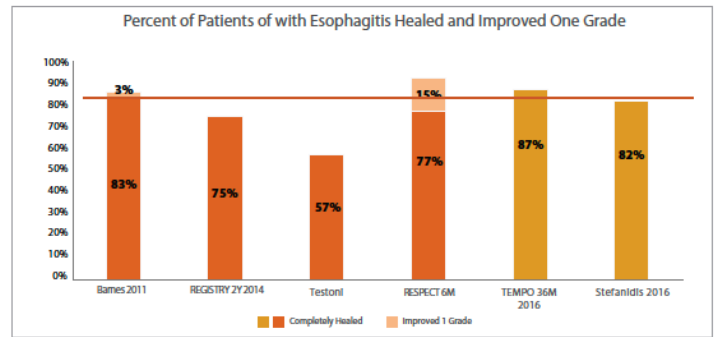
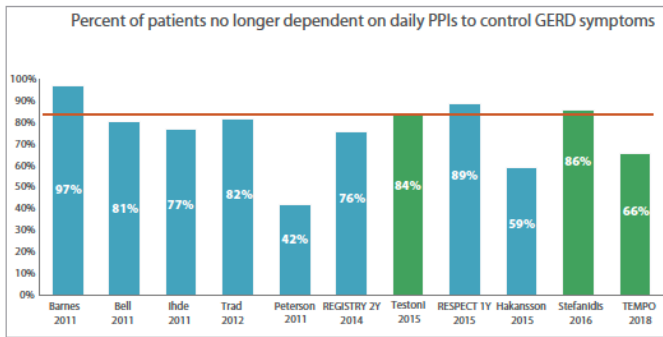


Data Supports GERD Treatment Gap Option



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

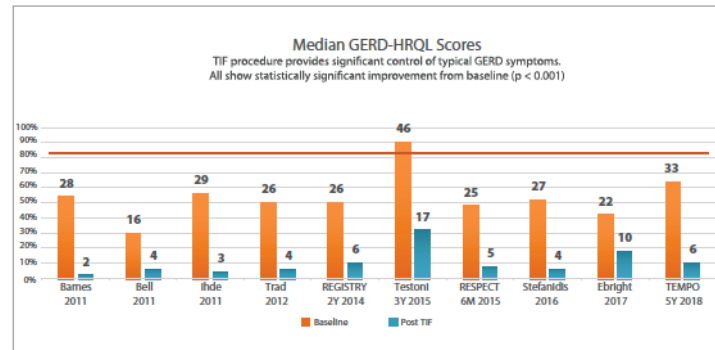
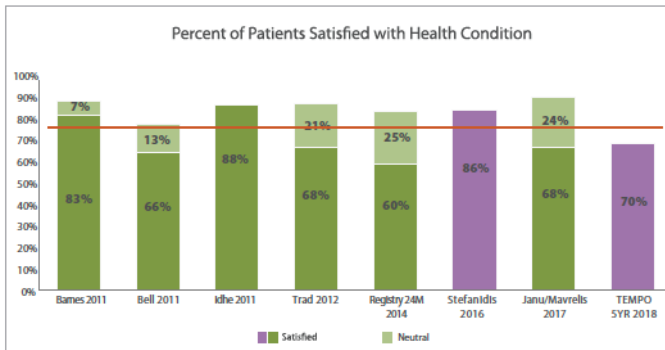
Weighted incidence is 78.35% across 3 studies follow-up > 59 mo in 120 patients

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

