EndoGastric Solutions®

The TEMPO trial at 5 years: Transoral fundoplication (TIF 2.0) is safe, durable and cost-effective

Surgical Innovation

February, 2018

NP02395-04A

TEMPO: TIF EsophyX vs. Medical PPI Open Label Trial

EndoGastric Solutions

Primary Endpoints: Elimination of *troublesome* (per Montreal Consensus definition) regurgitation and atypical symptoms will be stable between 1-, 3- and 5 year follow-up.
Secondary Endpoints: Improvement in GERD-HRQL score will be stable between 1-, 3- and 5 year follow-up.

- Randomized, multicenter, crossover comparative study
- 7 centers in the U.S.A. (**4** Surgical practices, **3 GI**)
- IRBs approved study
- Enrollment from June 2012 to August 2012
- Target randomization ratio 2:1 (TIF:PPI)
- All patients (n=21) randomized to PPI group elected to undergo TIF after 6-month visit

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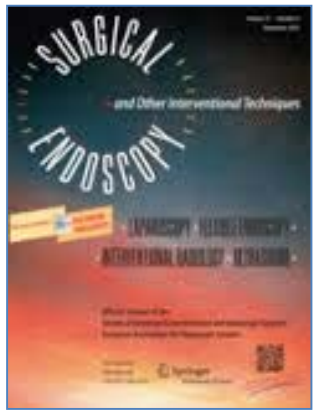
TEMPO: Study Patients

- Troublesome regurgitation and/or atypical symptoms while on daily PPI therapy
- Abnormal 48-h pH OFF PPIs (time pH<4 >5.3% of total)
- GERD duration > 1 year
- Daily PPI use > 6 months
- Hill grade I and II at gastroesophageal junction
- Esophagitis grade A or B
- BMI ≤ 35
- Hiatal hernia ≤ 2cm in axial length and/or in greatest transverse dimension
- 44 patients completed 5 year follow-up

3
Previous Published Papers

Surg Endosc (2017) 31:2498–2508
DOI 10.1007/s00464-016-5252-8

Transoral fundoplication offers durable symptom control for chronic GERD: 3-year report from the TEMPO randomized trial with a crossover arm



Trad et al. BMC Gastroenterology 2014, 14:174
http://www.biomedcentral.com/1471-230X/14/174

BMC Gastroenterology

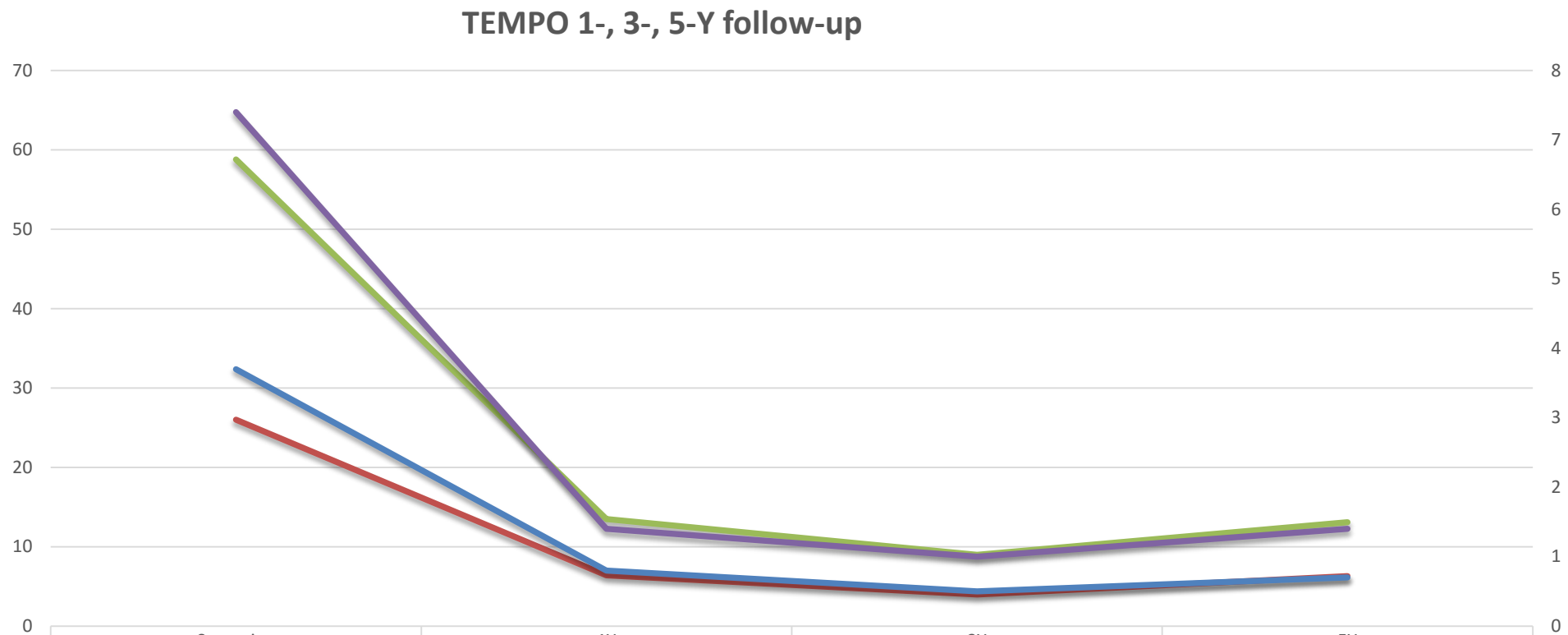
RESEARCH ARTICLE Open Access

Efficacy of transoral fundoplication for treatment of chronic gastroesophageal reflux disease incompletely controlled with high-dose proton-pump inhibitors therapy: a randomized, multicenter, open label, crossover study

Original Clinical Science

Transoral Incisionless Fundoplication Effective in Eliminating GERD Symptoms in Partial Responders to Proton Pump Inhibitor Therapy at 6 Months: The TEMPO Randomized Clinical Trial

TEMPO: Quality of Life Measurements



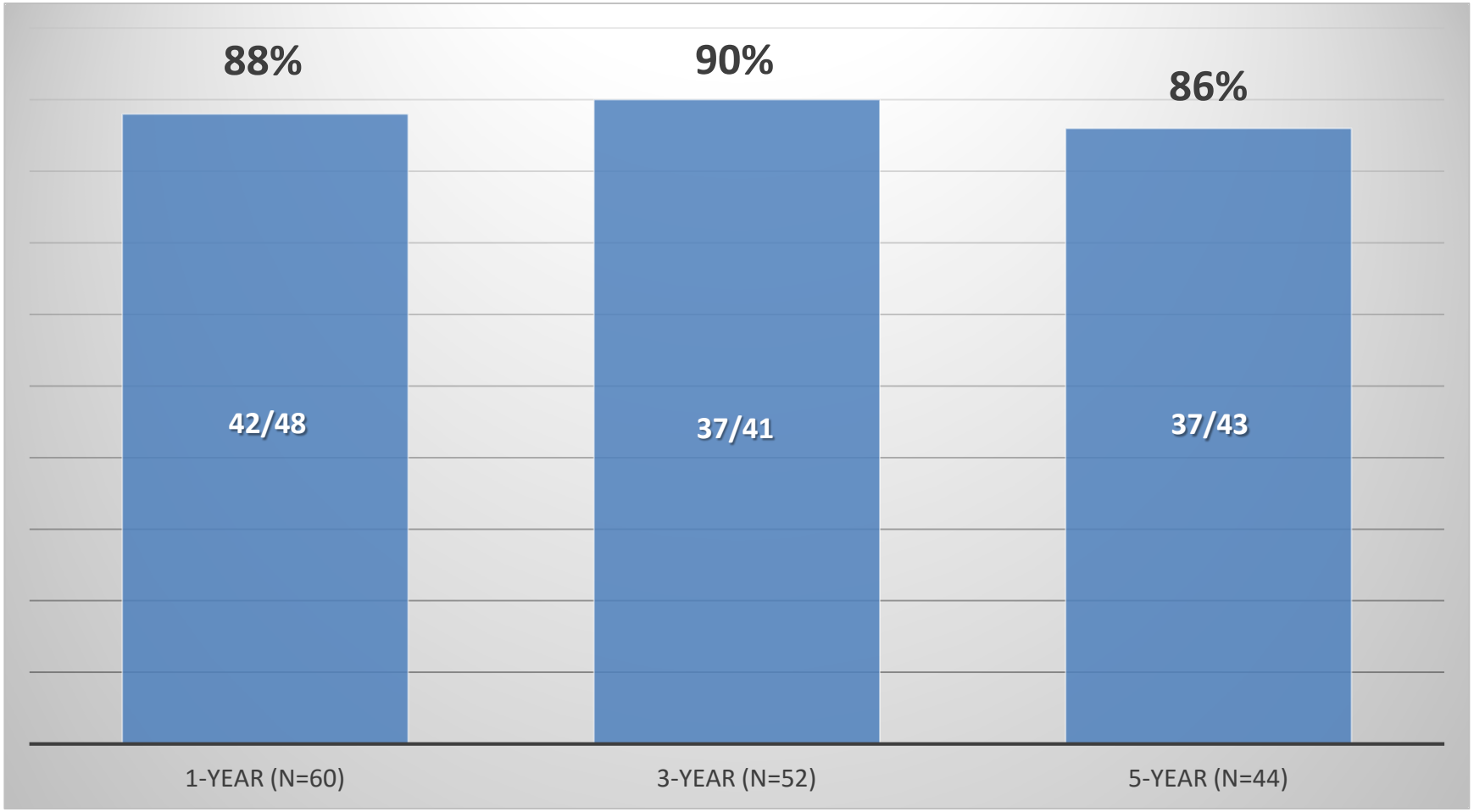
	Screening	1Y	3Y	5Y
GERD-HRQL	32.8	7.1	5	6.8
RSI	26	6.4	4	6.3
Regurgitation (from RDQ)	3.7	0.6	0.5	0.7
RDQ	3.7	0.8	0.5	0.7

Reference: Trad, et al.; Surg Innov. 2018 Feb 6 [Epub ahead of print]

TEMPO: Elimination of Regurgitation

Sustained elimination of regurgitation up to 5-years

P = NS between 1-, 2- and 3-Year FU



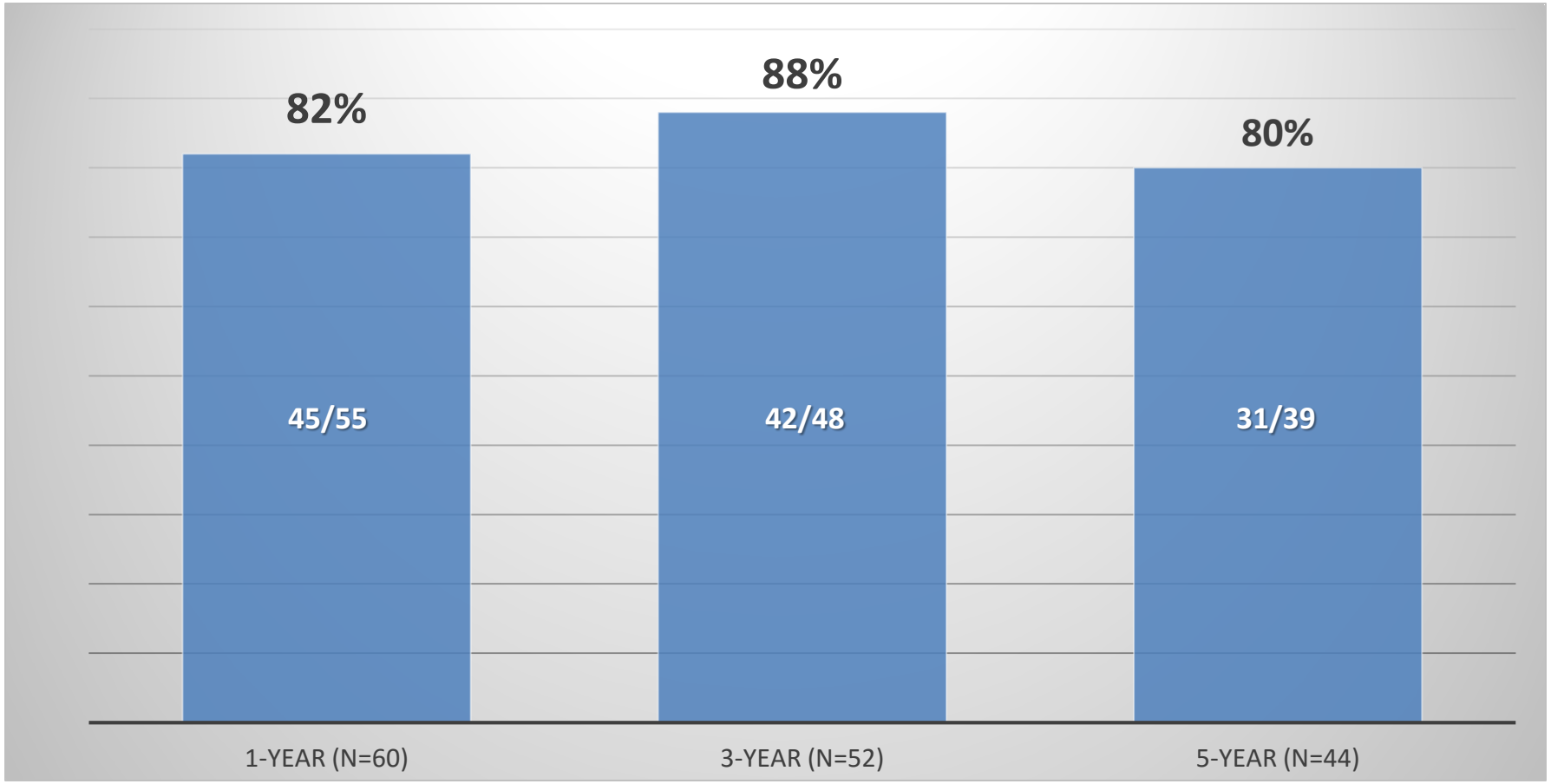
Comparison vs screening ON PPIs

Reference: Trad, et al.; Surg Innov. 2018 Feb 6 [Epub ahead of print]

TEMPO: Elimination of Atypical Symptoms

Sustained elimination of atypical symptoms (RSI≤13) up to 5-years

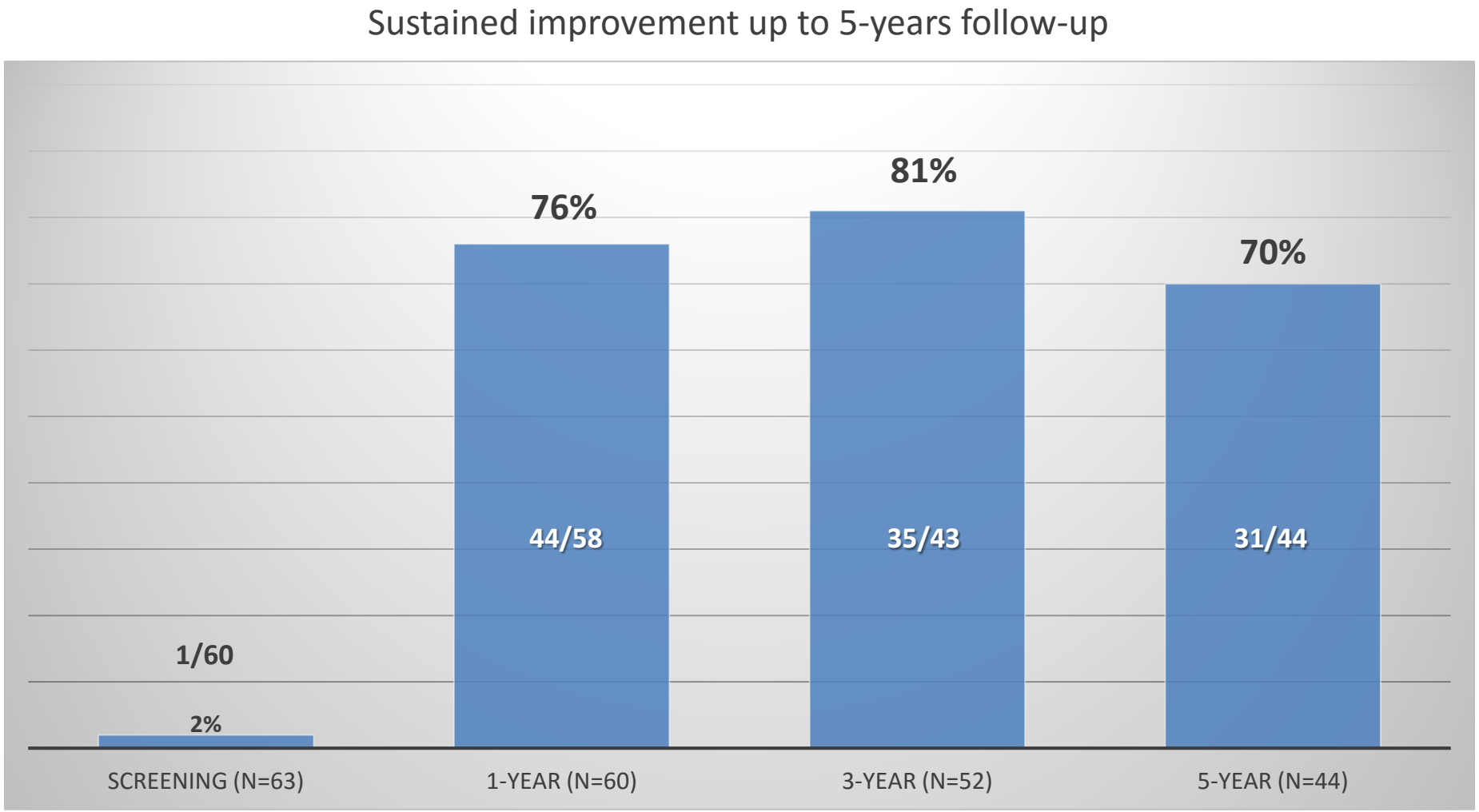
P = NS between 1-, 3- and 5-Year FU



Comparison vs screening ON PPIs

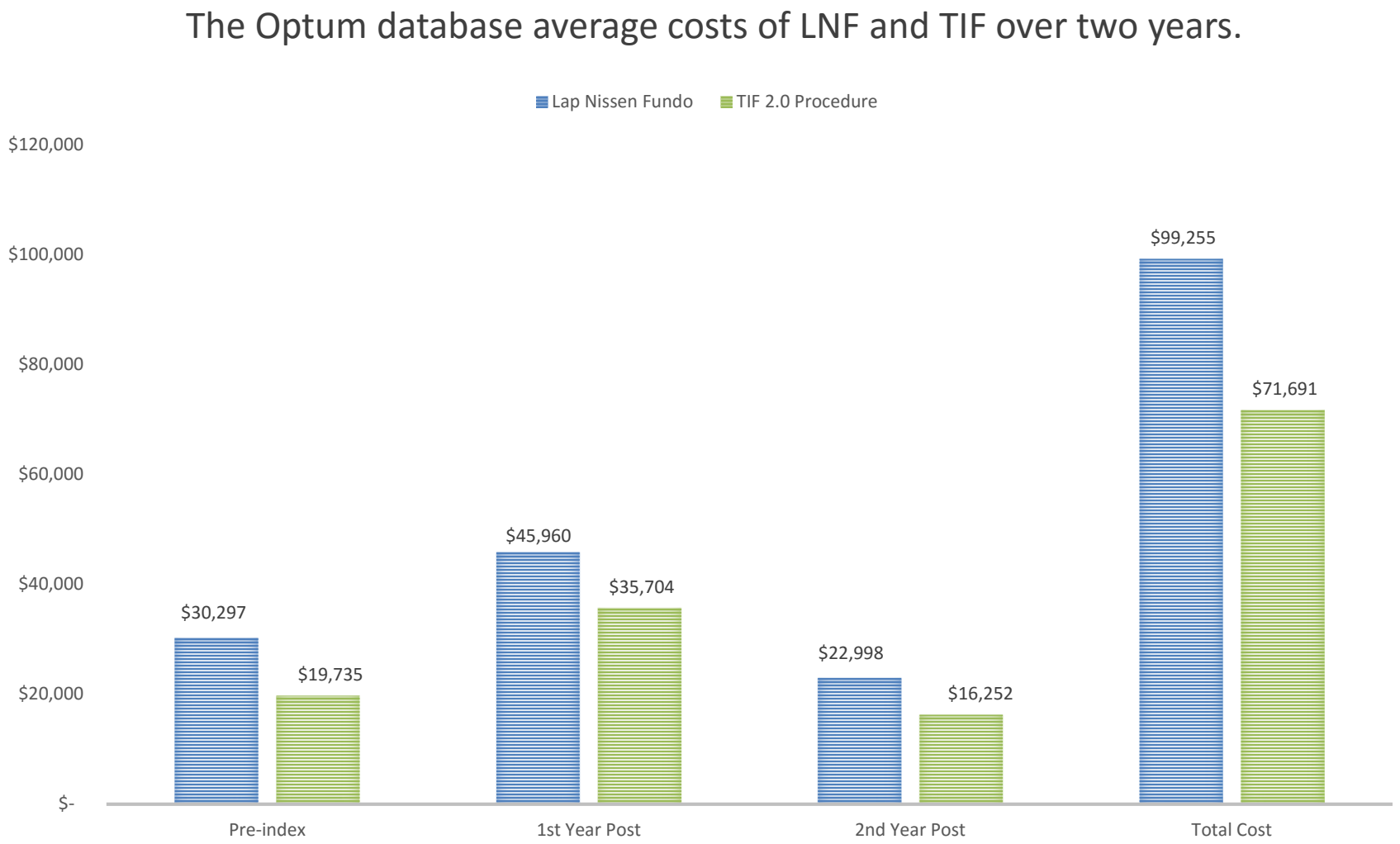
Reference: Trad, et al.; Surg Innov. 2018 Feb 6 [Epub ahead of print]

TEMPO: Satisfaction with Current Health Condition



Reference: Trad, et al.; Surg Innov. 2018 Feb 6 [Epub ahead of print]

TEMPO: LNF vs. TIF Total Cost Data



Reference: Trad, et al.; Surg Innov. 2018 Feb 6 [Epub ahead of print]

TEMPO: 5 Year Conclusions

EndoGastric Solutions

The TEMPO trial at 5 years:
Transoral fundoplication (TIF 2.0)
is safe, durable and cost-effective

- Five years after undergoing TIF 2.0 procedure, the great majority of TEMPO trial patients experienced durable elimination of all types of troublesome GERD manifestations, including regurgitation and atypical symptoms.
- There were no serious adverse events or any safety concerns associated with the TIF 2.0 procedure.
- In the appropriate patient population, TIF 2.0 procedure is a cost-effective alternative to laparoscopic Nissen fundoplication.
- The TIF procedure is a proven endoscopic alternative to control troublesome GERD symptoms in well-selected patients with troublesome symptoms on maximum dose PPI before procedure
- The TIF procedure should be considered as a first-line treatment modality for subset of GERD patients with uncontrolled symptoms on PPIs