



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

Surgical Innovation  
February, 2018

**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

William E Barnes, MD, FACS (S)	Livingston Hospital, KY
Mark A Fox, MD, FACS (S)	Crossville Medical Group, TN
Jeffrey A Heise, MD FACS (S)	Hancock Regional Hospital, IN
Mamoon Raza, MD (GI)	Indiana Medical Research, IN
Ahmad B Shughoury, MD (GI)	Internal Medicine Associates, IN
Peter G Mavrelis, MD (GI)	
Gilbert Simoni, MD (GI)	Advanced Gastroenterology, CA
Karim S Trad, MD, FACS (S)	GWU School of Medicine, DC
Principal investigator	Reston Surgical Associates, VA

- 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



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**

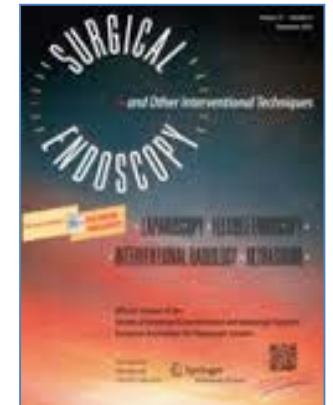
Tsai et al. BMC Gastroenterology 2014, 14:174  
<http://www.biomedcentral.com/1471-2202/14/174>



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

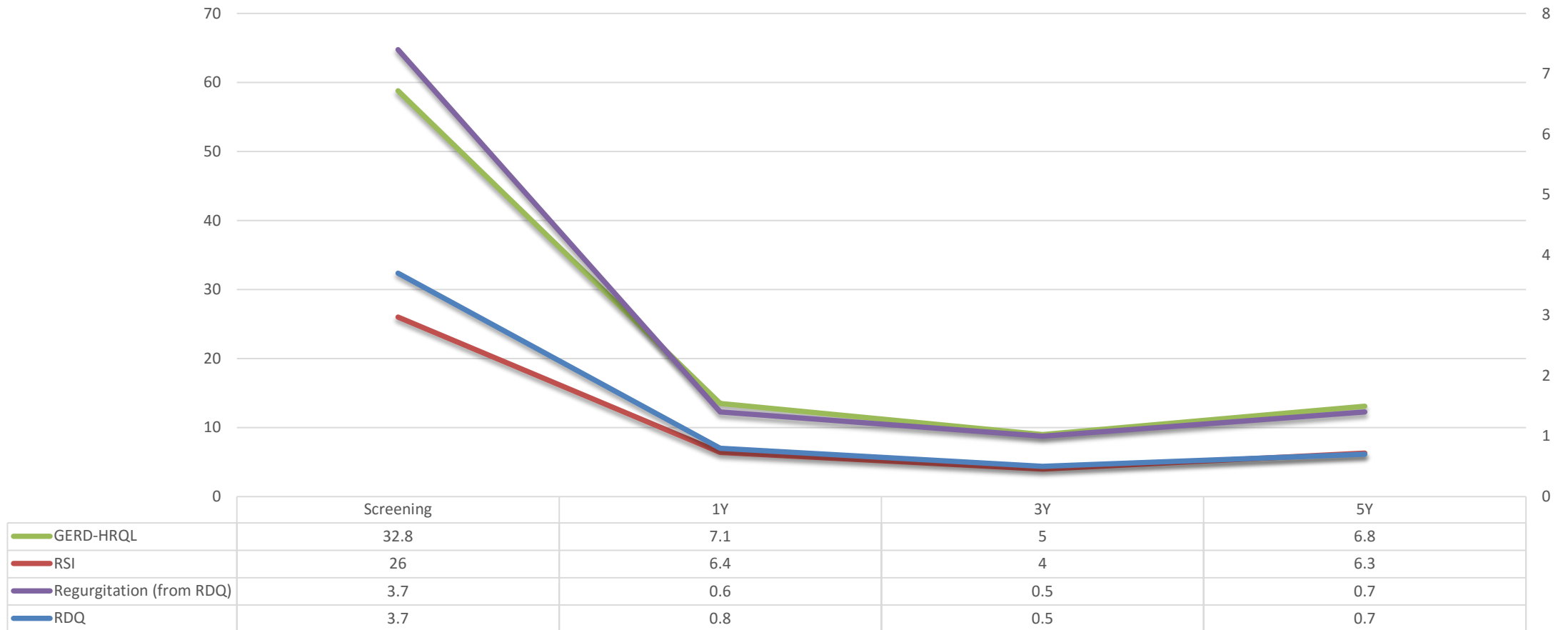


Original Clinical Science

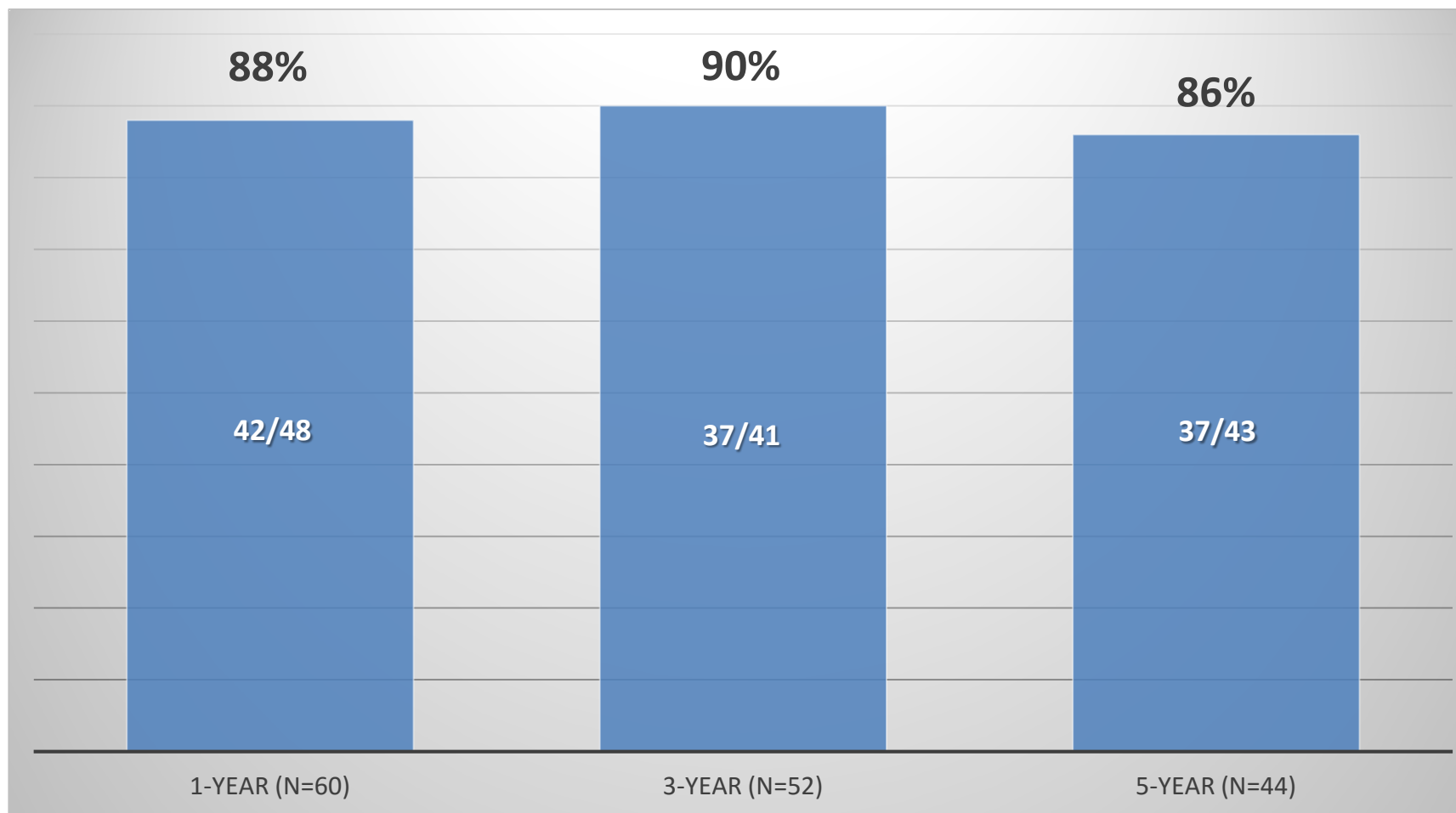
**Transoral Incisionless Fundoplication Effective in Eliminating GERD Symptoms in Partial Responders to Proton Pump Inhibitor Therapy at 6 Months: The TEMPO Randomized Clinical Trial**



### TEMPO 1-, 3-, 5-Y follow-up



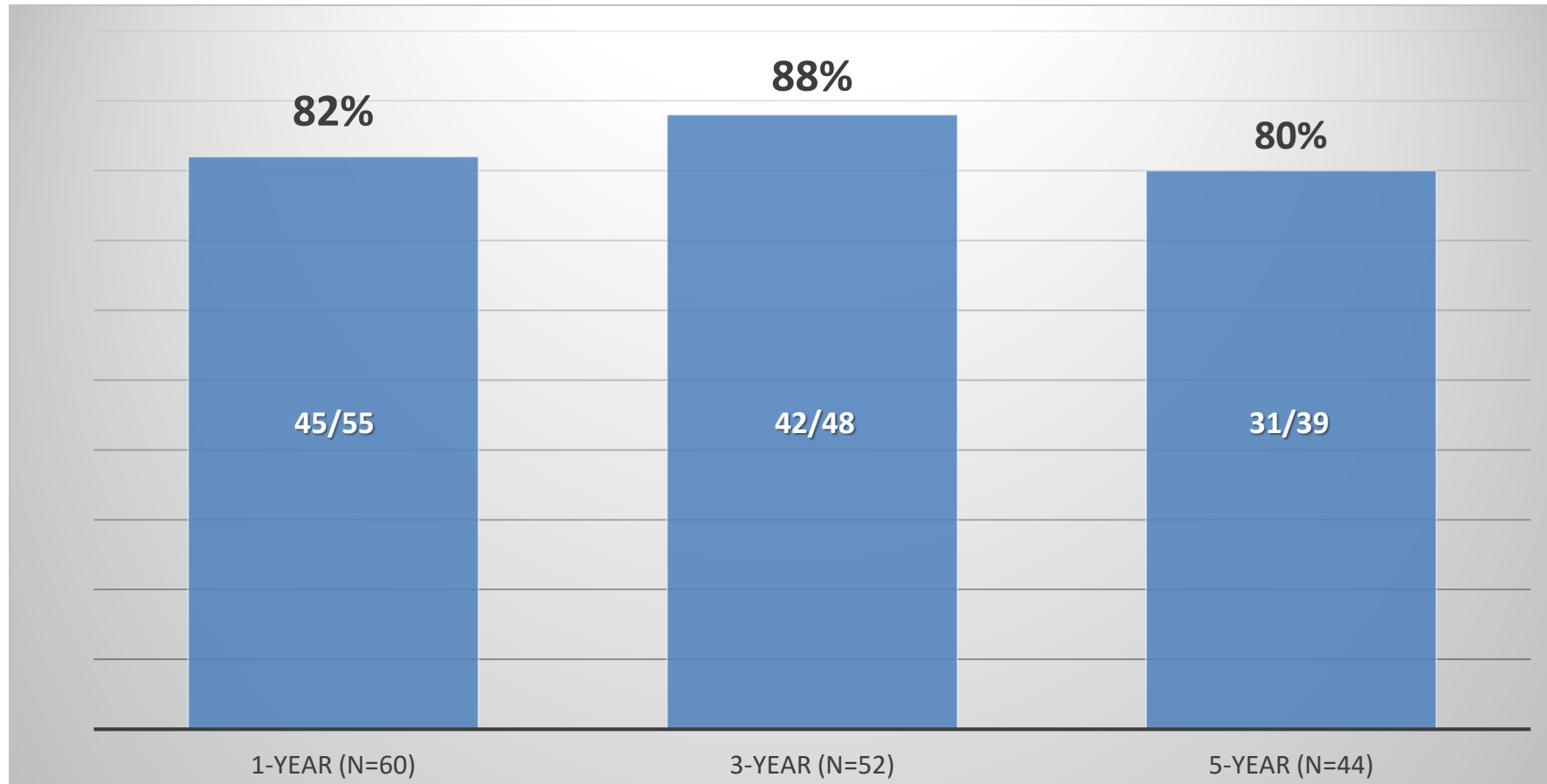
Sustained elimination of regurgitation up to 5-years  
*P* = NS between 1-, 2- and 3-Year FU



Comparison vs screening ON PPIs

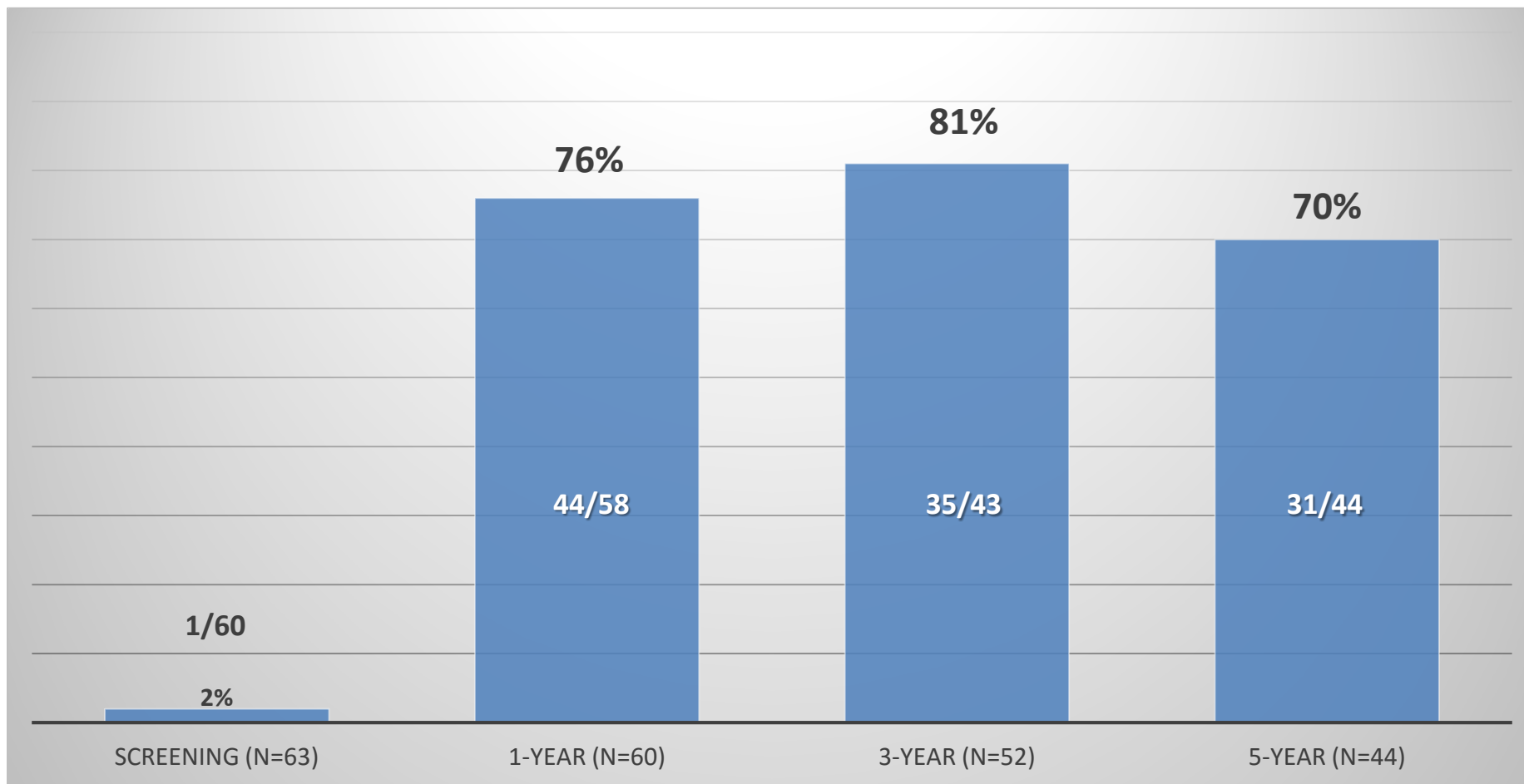
Sustained elimination of atypical symptoms (RSI $\leq$ 13) up to 5-years

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

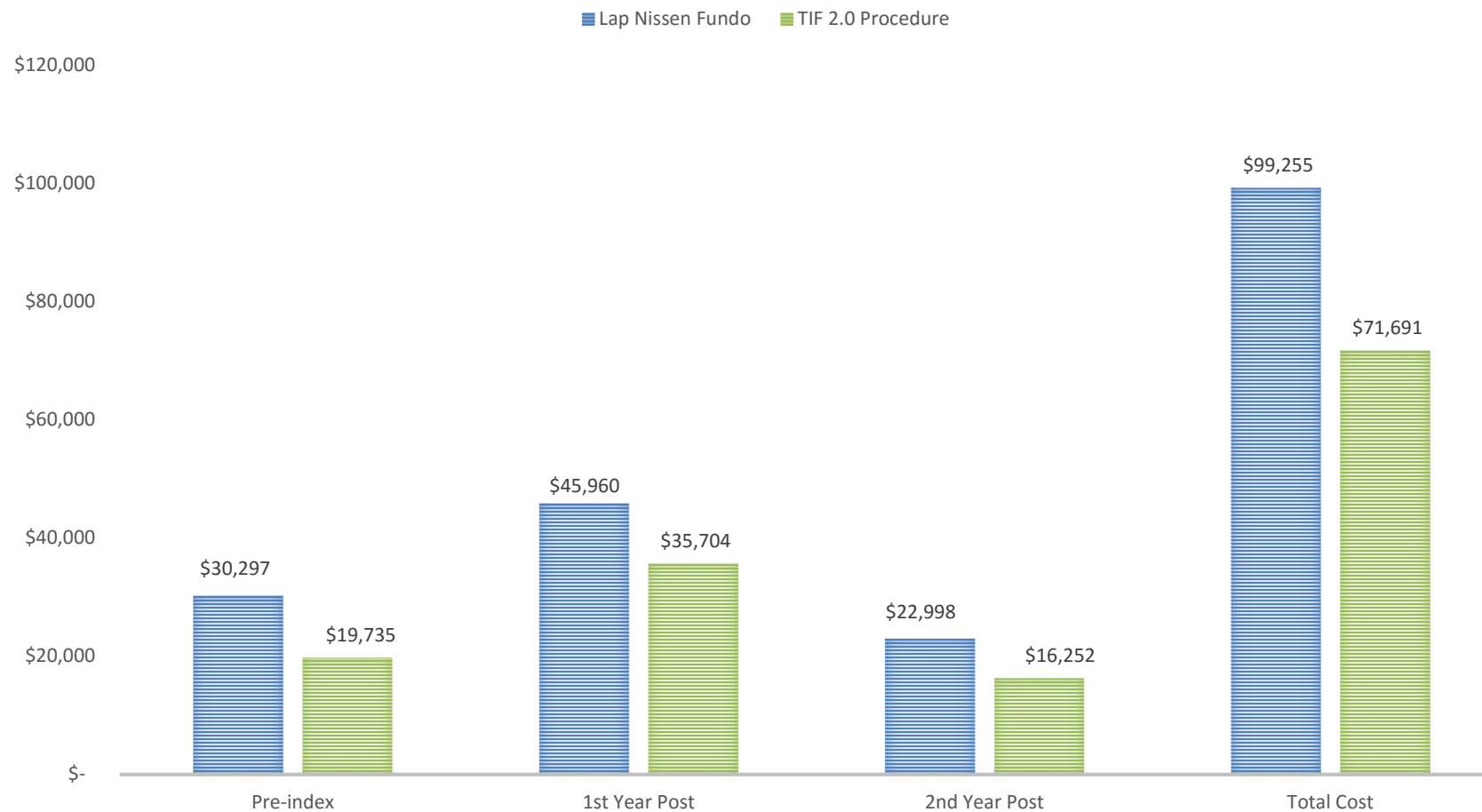


Comparison vs screening ON PPIs

Sustained improvement up to 5-years follow-up



The Optum database average costs of LNF and TIF over two years.





**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