

# pH Scores in Hiatal Repair with Transoral Fundoplication (TIF 2.0)



## BACKGROUND

Transoral incisionless fundoplication is an alternative to traditional laparoscopic funduplications. Recently, hiatal hernia repair combined with transoral incisionless fundoplication has become an accepted modification of the original procedure; however, outcomes information, particularly objective pH monitoring, has been sparse. This was a single-site retrospective analysis of subjective and objective outcomes of transoral incisionless fundoplication combined with hiatal hernia repair.

## METHODS

Ninety-seven consecutive patients presenting for reflux evaluation were reviewed for outcomes after evaluation and treatment. Fifty-five patients proceeded to hiatal hernia repair with transoral incisionless fundoplication. Twenty-nine patients (53%) were found to have matched preoperative and postoperative validated surveys and pH evaluations.

## RESULTS

There were no serious complications. The mean follow-up was 296 days. The mean Gastroesophageal Reflux Disease Health Related Quality of Life score improved from 33.7 to 9.07,  $P < .001$ . The mean Reflux Symptom Index score improved from 20.32 to 8.07,  $P < .001$ . The mean pH score improved from 35.3 to 10.9,  $P < .001$ . Twenty-two of the 29 patients were judged to have an intact hiatal repair with transoral incisionless fundoplication (76%). Of the 22 patients with an intact hiatal repair and intact fundoplication, 21 (95%) had normalized their pH exposure.

## CONCLUSION

In this retrospective review, hiatal hernia repair combined with transoral incisionless fundoplication significantly improved outcomes in patients with gastroesophageal reflux disease in both subjective Gastroesophageal Reflux Disease Health Related Quality of Life (GERD HRQL) and Reflux Symptom Index (RSI) measurements as well as in objective pH scores.

## KEY POINTS

1. Intact hiatal repair with intact transoral incisionless fundoplication led to normalization of pH scores in 21 of 22 patients (95%)
2. The transoral incisionless fundoplication has advantages over laparoscopic fundoplication due to the avoidance of the bloat syndrome and its reproducibility; this is the compelling argument for using the TIF 2.0 procedure at the time of laparoscopic hiatal repair
3. There were no serious adverse events, demonstrating safety in the combined approach
4. 29 patients (53%) were evaluated based on matched preoperative and postoperative assessments.
5. Among these 29 patients, the initial mean GERD HRQL score was 33.75 and the mean follow-up score was 9.07
6. Mean initial RSI score was 20.32 and the mean follow-up score was 8.07
7. Mean initial pH score was 35.3 and the mean follow-up score was 10.9
8. Overall, 22 of the 29 patients (76%) normalized their pH exposure
9. 7 patients (24%) had an elevated pH score. 6 of these patients were demonstrated to have defects in their repair. High pH scores were attributed to failure of the hiatal hernia repair in 5 of the 7 patients (71%) and due to poor fundoplication in one (14%). Three patients (11%) were found to have an intact fundoplication but also a recurrent hiatal hernia on an initial follow-up endoscopy

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6333564/>

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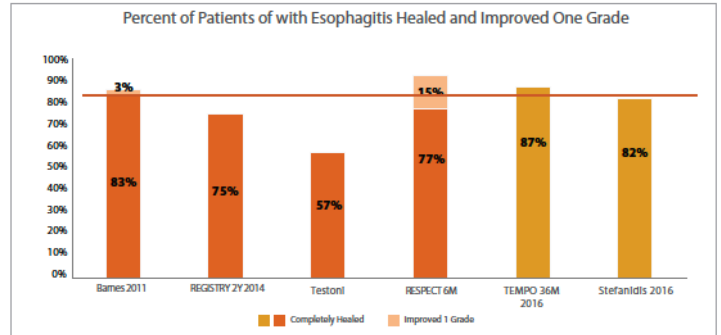
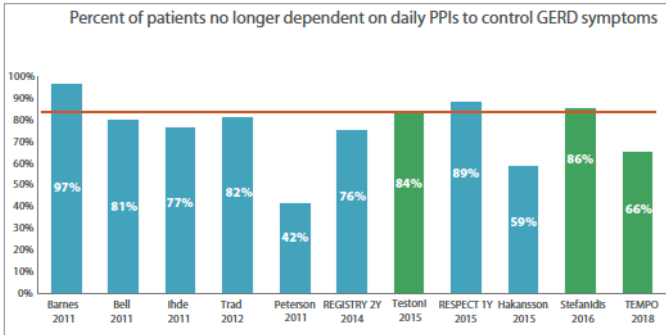


# Data Supports GERD Treatment Gap Option



**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

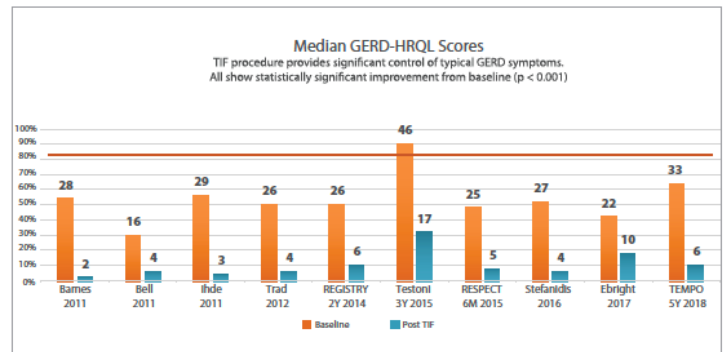
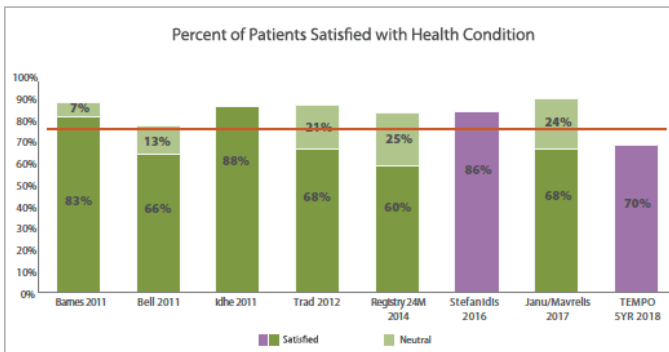
Weighted incidence is 78.35% across 3 studies follow-up > 59 mo in 120 patients

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

