Laparoscopic Hiatal Hernia Repair and Transoral Incisionless Fundoplication with EsophyX Device
Efficacy and Safety in Two Community Hospitals 99 Patients

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Introduction

GERD unresponsive to medical therapies can be treated by laparoscopic Nissen fundoplication or endoluminal techniques. We describe our experience using the TIF procedure with the EsophyX device. The TIF procedure is not indicated in patients with a hiatal hernia larger than 2 cm. Performing a hiatal hernia repair (HHR) in those cases will make a patient eligible for a TIF procedure. [1] HHR followed immediately by the TIF procedure under the same anesthetic session is called a Hybrid-TIF (HTIF). This study examines the safety and efficacy of this approach.

Methods

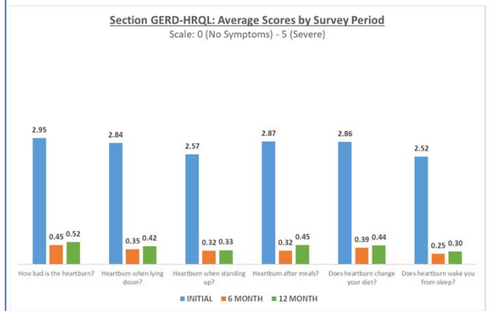
Prospective data were collected from patients who underwent HTIF at two 300-bed community hospitals. Questionnaires were administered before the procedure, and mailed at 6- and 12-months post concomitant procedure. They were:

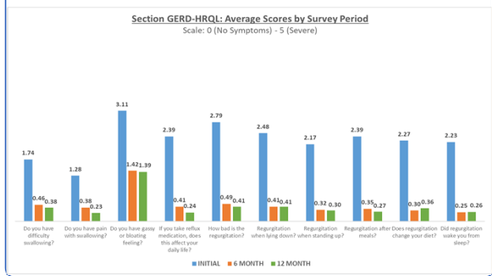
- GERD-Health Related Quality of Life (GERD-HRQL) [2]
- Reflux Symptom Index (RSI) [3]
- GERD Symptom Score (GSRS) [4]

At site 1 the same surgeon (PJ) performed HTIF. At site 2 three general surgeons (TG, JS, DS) performed HHR and four gastroenterologists (PM, BS, DH, KV) performed the TIF procedures.

Results

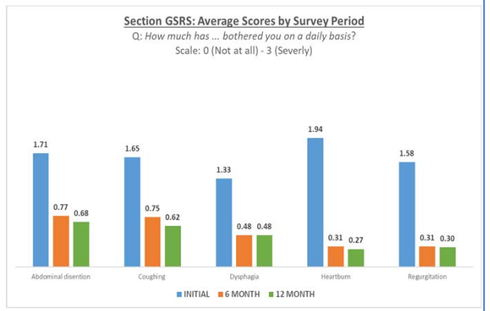
Ninety-nine patients were enrolled, 49 from site 1, 50 from site 2. All were symptomatic on PPI medications with hiatal hernias between 2 and 5 cm. The avg. age was 53, 56% female, and avg. BMI was 30. The questionnaire response rate was 73% at 6 mos., 67% at 12 mos., and 48% for both. Heartburn severity score (1-5) dropped from 2.95 to .45 at 6 mos. and .52 at 12 mos.

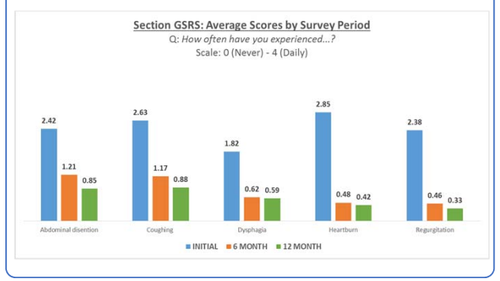




Other GERD-HRQL scores were improved 85% for all six heartburn questions and 7 regurgitation questions, while 50% improvement was noted for bloating, dysphagia and odynophagia.

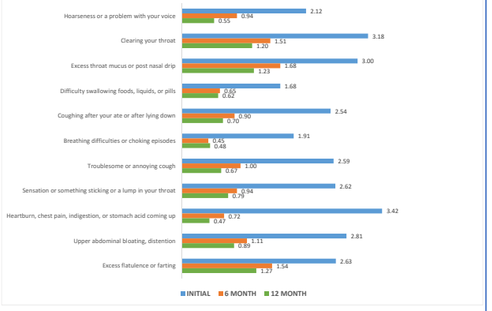
The atypical symptoms from the RSI scores for chest pain dropped from 3.42 to .72 at 6 mos. and .47 at 12 mos. Hoarseness, throat clearing, excess mucus, coughing, also improved as well, from 50% to 80%.

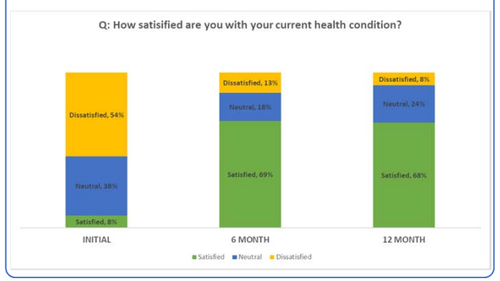




The GSRS questions on heartburn dropped from 2.85 to .48 at 6 mos. and .42 at 12 mos. and regurgitation showed 80% improvement while bloating and dysphagia improved by more than 50%.

All these results were durable at 6 and 12 mos. All measures were statistically improved at $p<0.05$. There were no adverse effects reported.

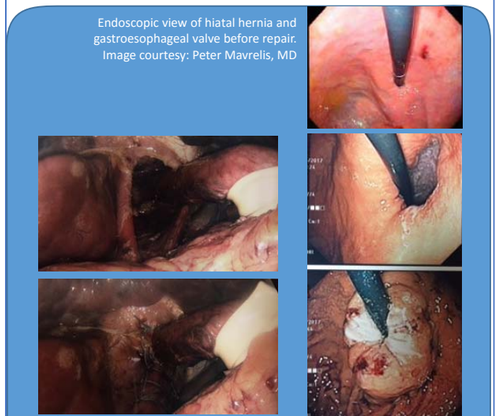




Discussion

TIF procedures can be safely performed immediately following HHR. Excellent symptom control occurred for heartburn and regurgitation with no long-term dysphagia or bloating. Most patients reported durable symptom control at 1 year post intervention. Similar results were obtained with either one operator (surgeon) performing both steps of the procedure or surgeons and gastroenterologists working as a team.

Endoscopic view of hiatal hernia and gastroesophageal valve before repair.
Image courtesy: Peter Mavrelis, MD



Left: laparoscopic view before and after hiatal hernia repair. Right: retroflex endoscopic view of GE junction before and after (TIF) procedure.
Images courtesy: Peter Janu, MD

References

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[3]Belafsky PC, Postma GN, Koufman JA Validity and reliability of the reflux symptom index (RSI). *Journal of Voice* 2002 16.2:274-9
[4]Allen CJ, Parameswaran K, Belda J, Anvari M; Reproducibility, validity and responsiveness of a disease-specific symptom questionnaire for gastroesophageal reflux disease. *Dis Esophagus* 2000 13: 265–270