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OUTPATIENT TRANSORAL INCISIONLESS FUNDOPLICATION (TIF 2.0) IS SAFE AND EFFECTIVE FOR TREATMENT OF PROVEN GASTROESOPHAGEAL REFLUX DISEASE (GERD) AND LARYNGOPHARYNGEAL REFUX DISEASE (LPRD): A SINGLE CENTER PROSPECTIVE COHORT STUDY

Esophageal Diseases
Endoscopy: Gastroesophageal Reflux (GERD)
Presented on Saturday, May 2, 2020 12:30 PM

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Published clinical trials of transoral incisionless fundoplication (TIF) in GERD patients using older devices and techniques reported symptom improvement, but with variable effects on proton pump inhibitor (PPI) cessation and esophageal acid exposure. There are limited data on the outcomes of modern TIF performed by a therapeutic endoscopist using improved devices and techniques. Aim: We evaluated the safety and efficacy of TIF performed for treatment of GERD. **Methods:** From September 2017, consecutive patients with refractory GERD/LPRD were enrolled into a prospective cohort study conducted in an academic tertiary referral center. Baseline clinical data, GERD questionnaires (GERD-HQRL and Reflux Symptom Index or RSI), endoscopy, Bravo wireless or pH impedance testing were recorded. TIF 2.0 (creation of a gastroesophageal plication with at least 270 degree wrap function and a 3 cm high pressure zone) was performed by a therapeutic endoscopist using the EsophyxZ or EsophyxZ+(Endogastric Solutions) devices under general anesthesia. Patients were observed then discharged when possible. We excluded patients with negative pH testing, > 2 cm hiatal hernia, Hill grade > 2, BMI > 35, jackhammer esophagus, moderate to severe ineffective esophageal motility, achalasia post per-oral endoscopy myotomy (POEM), and eosinophilic esophagitis. Patients with non-dysplastic Barrett's esophagus (BE) had ablation and achieved complete eradication prior to TIF. Treatment response was assessed at a minimum 6 months (with GERD surveys, EGD and Bravo pH testing) or last follow-up (GERD surveys). Efficacy was assessed by GERD phenotype. **Results**: Of 257 patients screened for TIF, 51 patients met criteria and underwent TIF (Table 1). Technical success rate=50/51(98%). Median procedure time was 48 min (QR 36-61) after the first 20 cases. All patients were discharge home from the PACU or after 23-hour observation. There were no treatment related serious adverse events. 3 (5.8%) patients had intra-procedural mild bleeding responding to endoscopic therapy. Median follow-up time was 11.5 months. In 31 evaluable patients with at least 6 months follow-up, symptom control in refractory GERD and LPRD was achieved in 90% (GERD-HQRL 90%) and 95% (RSI), respectively. PPI use was eliminated or reduced in 94%. Esophageal acid exposure time was normalized or reduced in 72%. Overall response rates in patients with reflux chest pain syndrome (n=4, 100%),regurgitation-predominant GERD (n=10, 90%), LPRD (n=4,100%), BE (n=8, 88%), >= 30 fasteners (n=13, 92%), >=3cm valve length n=13, 94%), and >270 degree valve circumference (n=14,93%) were high. 6(12%) patients required repeat TIF(n=3) or surgery(n=3) within 1 year. **Conclusions**: Our early experience suggests that TIF 2.0 is a viable, efficient, safe, and effective alternative intervention for selected patients with refractory GERD and LPRD.

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Table 1 Patient Characteristics

	All n=51
Mean age, SD	56.5 (SD 13.2)
% Male	36(71%)
Median hiatal hernia axial length (cm) < 2	0.5 (IQR 0-1)
Hiatal hernia = 0	17
Hiatal hernia = 1 cm	17
Hiatal hernia = 1.5 cm	2
Hiatal hernia = 2 cm	15
Median Hill grade	1 (IQR 1-2)
Prior surgical fundoplication	6(12%)
Indications for TIF	
Refractory GERD	26 (51%)
LPRD	4(9%)
Failed Nissen	5(9%)
PPI-averse	16 (31%)
NERD	37(72.6%)
Erosive esophagitis	13(25.5%)
History of Barrett's esophagus	17(33%)
Reflux chest pain syndrome	10(19.6%)
Regurgitation-predominant GERD	27(52.9%)
LPRD (extra-esophageal symptoms)	22(43.1%)
Chronic cough	9(17.6%)
TIF valve circumference >=300 deg	24(47%)
TIF valve length >= 3 cm	35(70%)

Table 1. Patient Characteristics

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Table 2 Treatment Response in Evaluable Patients

	No response or worse (0)	Partial (reduction <50% compared to baseline)	Partial (reduction between 50-<100% compared to baseline)	Complete
PPI use n=31	2(6.4%)	4(12.9%)	3(9.7%)	22(71%)
PPI use n=31	2(6.4%)	29(94%)		
GERD-HQRL (n=20)	2 (10%)			18 (90%)
RSI (n=31)	1(5%)			19(95%)
Symptom improvement N=31	1(3.3%)	3 (3(9.7%)	7(22.6%)	20(64%)
Acid exposure by pH testing (N=25)	7(28%)	3(12%)	2(8%)	13(52%)
Acid exposure by wireless of catheter-based pH testing (N=25)	7(28%)	18(72%)		

Table 2. Treatment Response in Evaluable Patients With At Least 6 Months of Follow-Up Post TIF

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