

Evolution and Outcome of Eight Patients Undergoing Treatment of Gastroesophageal Disease by Esophyx

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Abstract

Background: Gastroesophageal reflux disease (GERD) is arguably the most common disease encountered by the gastroenterologist. It is mainly caused by defects in the lower esophageal sphincter (LES) that induces spontaneous transient LES relaxations (tLESRs). This is a chronic condition with typical and atypical, sometimes troublesome manifestations requiring long term treatment. Anti-reflux surgery is an alternative option. The TIF (transoral incisionless fundoplication) procedure by offering some advantages over surgery could be recommended for patients whose symptoms recur upon discontinuation of the medications. This study intended to assess the safety and efficacy of TIF for treating GERD.

Methods: A prospective trial was conducted at Lebanese Hospital Geitaoui University Medical Center and Middle East Institute of Health in Lebanon, on 8 patients, age 28-55 years, with chronic GERD, symptoms (>5 years), undergoing Esophyx procedure and followed for 1 year after their procedure. Information concerning the patients was gathered using an international questionnaire (GERD-HRQL, Health Related Quality of Life questionnaire) filled by the treating physician.

Results: When compared to scores before TIF and without medications, the GERD-HRQL scores were significantly reduced one year after the procedure. Regurgitation experienced was reduced to 62.5% compared to 75% while patients were off PPI. Symptoms free (GERD-HRQL score ≤ 12) achieving complete cessation of medications, were reported by 25% of patients. Overall 37.5% of patients were satisfied, 12.5% neutral, and 50% less satisfied with their results.

Keywords: Anti-reflux surgery; Endoscopy; Esophyx; Gastroesophageal reflux disease; Transoral incisionless fundoplication

Introduction

The need for a long term treatment of gastroesophageal reflux disease (GERD) has become increasingly apparent during the past decade and a half as a result of the growing prevalence and incidence of this chronic disease [1]. The likelihood of developing GERD increases with the severity of anatomic change and dysfunction of the gastroesophageal (GE) junction, which represents the primary defense against reflux of gastric content into the esophagus. Restoration of the anti-reflux competence of the GE junction at the anatomic and physiologic levels is critical for effective long term treatment of GERD [2]. Given the growing prevalence and incidence of this chronic disease during the past decade, the high probability of symptoms recurrence upon discontinuation of medications, the need for a long term treatment has become increasingly apparent [1]. The management should also take into consideration the patient compliance, satisfaction and the cost of the treatment. Among the alternative treatments available to pharmacologic anti-secretory therapies, the more advanced options are the anti-reflux surgery and the TIF procedure. Anti-reflux surgery (ARS) is considered in terms of patient satisfaction, clinical outcome, as effective as anti-secretory therapies. It offers an advantage of cost reduction in the long term management of chronic GERD [3]. However, side-effects of the anti-reflux

fundoplication procedures frequently compromise otherwise excellent postsurgical results [4]. Persistent dysphagia, inability to belch and vomit, and increased bloating and flatulence are common side effects that may persist for more than 6 months following surgery and prove to be difficult to treat [4]. The TIF (transoral incisionless fundoplication) procedure follows the well-established principles of open and laparoscopic ARS and delivers similar results in an innovative way. With no incision, no dissection and excellent safety profile, the procedure is performed with fewer complications than conventional ARS [5]. A novel device the Esophyx system with SerosaFuse fasteners (EndoGastric Solutions, Redmond, WA, USA) was designed to reconstruct a valve through tailored delivery of multiple fasteners during a single-device insertion [6,7]. This article presents results at 12 months from a prospective trial with 8 patients and was intended to further evaluate the safety and efficacy of the TIF procedure using the Esophyx system.

Patients and Methods

The safety and efficacy of TIF for treating GERD is evaluated in a prospective trial for one year conducted at Lebanese Hospital, Geitaoui University Medical Center and Middle East Institute of Health in Lebanon, under a common protocol. Patient's names remained anonymous. Informed consent was obtained before enrolling patients in the study.

Patient selection

Eight patients were enrolled in the study, age 28-55 years, from both sex, with chronic GERD symptoms (>5 years), who were responsive on continuous daily PPI medication, and whose symptoms recurred upon interruption of therapy for 14 days, undergoing EsophyxX procedure and followed for one year after their procedure. Gathered information covered their age, gender, GERD duration, PPI use, results of preoperative endoscopy, response following endoscopic therapy, as well as the type of adverse reactions experienced. The exclusion criteria were Hiatal hernia greater than 2 cm, severe erosive esophagitis (grade D in the Los Angeles classification), esophageal strictures or varices, intestinal metaplasia and Barrett's esophagus, previous esophagogastrectomy, pregnancy, obesity with BMI >35 kg/m² at high anaesthesia risk (ASA class 3 or greater). The validated 10 question GERD-HRQL questionnaire was used to assess patient quality of life as primary endpoint and to evaluate patient satisfaction regarding heartburn-related symptoms [8-13].

Patients were on PPI's therapy during the initial screening phase, then discontinued for 14 days. While off all GERD medications, the GERD-HRQL questionnaire was re-administered. This evaluation was repeated 12 months after the procedure by using the questionnaire score.

Procedure details

The TIF procedure using the Esophyx device was designed to create full-thickness serosa-to-serosa plications and construct valves 3 cm to 5 cm in length and 200°C to 300°C in circumference. The procedures were performed following a TIF 2 protocol under general anesthesia with transoral intubation by the gastroenterologist by controlling the implantation of fasteners using the Esophyx device, operating the endoscope and ensuring continuous direct visualization. The device is inserted trans-orally into the esophagus with the patient in the left lateral position. The hiatal hernia, if present, is reduced by returning the squamo columnar junction to its natural position below the diaphragm using a built-in vacuum invaginator. During a single insertion, a valve similar to that created through anti-reflux surgery is reconstructed by retraction of full-thickness plications and tailored placement of multiple fasteners circumferentially around the GE junction starting on the greater curve side of the valve. Patients were instructed to consume a liquid diet during the first 2 weeks and a soft diet during the following 4 weeks. In the event of symptom recurrence requiring medication, a "step-down" protocol was adopted; and patients were returned to their pre-procedure dose of PPIs and then weaned from them if possible.

Results

The total GERD-HRQL scores were calculated by summing up the answers to nine questions; scores ranged between 0 (no symptoms) and 45 (worst symptoms). The GERD-HRQL score was considered clinically significant if there is ≥ 50% improvement in the total scores compared to the baseline off PPI's. Patient satisfaction with their current health condition was evaluated based on question 10 as either "satisfied", "neutral," or "dissatisfied". Regurgitation was assessed as present or absent by a separate direct question. Secondary effectiveness endpoints were PPI usage. The enrolled 8 patients were 28 years to 55 years old (median 33.7 years). Overall, the patients were symptomatic for a median of 6.4 years (3-10 years) and were receiving PPI medication on daily basis for more than 4.5 years (3-7 years). Their

symptoms were responsive to PPI therapy, as judged by GERD-HRQL scores of ≤ 12 while on PPI therapy, however symptoms recurred after 14 days discontinuation of PPI therapy (GERD-HRQL score ≥ 20 and a difference of ≥ 10 between the scores on and off PPI) (Table 1).

Patient	On PPI treatment		After discontinuation of PPI 's for 14 days	
	GERD-HRQL score (all<12/45)	Patient satisfaction	GERD-HRQL score (all>20/45)	Patient satisfaction
1	6	Dissatisfied	28	Dissatisfied
2	5	Neutral	25	Dissatisfied
3	10	Dissatisfied	35	Dissatisfied
4	5	Neutral	23	Dissatisfied
5	5	Neutral	27	Dissatisfied
6	4	Satisfied	28	Dissatisfied
7	5	Neutral	19	Dissatisfied
8	4	Satisfied	17	Dissatisfied

Table 1: GERD-HRQL scores and patient's satisfaction while on PPI and 14 days after discontinuation of PPI treatment.

The median GERD-HRQL scores pre-TIF increased (worsened) after discontinuation of PPIs from 5.5 (4-10) to 24 (11-35). Before TIF, 100% of patients were taking either full-dose or half-dose PPIs on a daily basis (Table 1). While taking PPIs, 2 (25%) patients were satisfied, 4 (50%) neutral, and 2 (25%) dissatisfied with their health condition compared to 100% dissatisfied after discontinuation of PPIs. While on PPI treatment only 2 patients experienced regurgitation (25%), compared to 6 patients off PPI (75%). Evaluating our patients by the GERD-HRQL questionnaire 1 year after Esophyx treatment showed the following results presented in Table 2.

Patients	HRQL score	Regurgitation	Patient satisfaction	PPI use
1	3	Present	Dissatisfied	Daily
2	2	Absent	Satisfied	None
3	13	Present	Dissatisfied	Occasional (once/week), then daily at 18 months
4	5	Present	Neutral	Occasional (full dose 2-3 days/week after 2 months)
5	3	Absent	Satisfied	none
6	0	Present	Dissatisfied	Daily
7	3	Absent	Satisfied	Occasional (once/week after 1 year)
8	1	Present	Dissatisfied	Daily

Table 2: Clinical results at 12 months.

Regurgitation experienced was reduced to 62.5% compared to 75% while patients were off PPI. Complete symptom elimination (GERD-HRQL score ≤ 12) was experienced by 25% of patients. 37.5% of patients were satisfied, 12.5% neutral, and 50% dissatisfied with their health condition. 25% of patients were able to stop daily PPIs use (Table 2). To note that side effects including dysphagia, gas bloat haven't been reported by our patients.

Discussion

The adequate and persistent control of symptoms in chronic gastroesophageal reflux disease (GERD) patients remains a therapeutic concern despite the potent effect of the medications available. This prospective study shows that TIF was better in controlling symptoms compared to PPIs. After one year follow-up, patients were reported to be off PPIs in 25% of cases. EsophyX offers advantages over surgery [14-17], in particular the absence of incision and thus a faster remission, as well as fewer complications in the short and long term compared to the undesirable side effects associated with laparoscopic anti-reflux procedure compromising the results in some patients. Currently published literature suggests that incidence of persistent side effects after TIF is low [4-6]. This technique does not affect other future therapeutic options. Our results must be interpreted cautiously considering the limitations of this study, most notably the small sample of 8 patients only, the two centres, two gastroenterologists study; follow-up grossly observational; unique use of subjective measures of GERD severity by GERD-HRQL score (without follow up by endoscopy), relative short follow up duration (1 year) and restriction to sub-groups of GERD patients [18-21].

However we felt that reporting these encouraging short-term results is reasonable given the large number of patients suffering from this chronic disease requiring long term treatment that have an impact on health care cost, yet some of them remain unsatisfied even with the daily use of medications.

Conclusion

TIF (EsophyX) is an effective solution for the treatment of reflux disease patients particularly in those who remain unsatisfied despite on continuous medical treatment, and an alternative to anti-reflux surgery with the likelihood of developing postsurgical side effects. All the patients who have benefited from this technique had a hiatal hernia of less than two cm. Our results were based on clinical symptoms because we did not realize a control PH-study. We believe that longer follow-up is needed to confirm the maintenance of the results shown in our study. Finally we think that new generations of devices offering easier maneuverability and therefore better results would be most welcome.

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