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BRIEF COMMUNICATION

Antireflux Mucosectomy Band (ARM-b) in Treatment of Refractory Gastroesophageal Reflux Disease After Bariatric Surgery

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Abstract

Laparoscopic sleeve gastrectomy has become the most commonly used bariatric surgery worldwide. However, there are a proportion of patients who present with a refractory GERD after this procedure. In these patients, when surgical conversion to RYGPB is not possible or declined, we propose to describe the results of an endoscopic antireflux mucosectomy band (ARM-b) technique in 6 LSG patients with refractory GERD. The technical feasibility was 100%; 5 out of 6 patients had a clinical response with a reduction of the GERD-HRQL score of > 50%. Two patients had adverse events: one esophageal stricture and one benign bleeding. ARM-b is feasible and potentially effective to treat patients with refractory GERD after LSG.

Keywords Laparoscopic sleeve gastrectomy · Sleeve · GERD · Reflux · Gastroesophageal reflux disease · Bariatric surgery · ARM · ARMS · ARMb · ARM-b · Antireflux mucosectomy band · Antireflux mucosectomy band ablation · Antireflux mucosectomy ablation · Mucosectomy · EMR · Endoscopy · PPI-refractory GERD · Refractory GERD · GERDQ · GERD-HRQL

Introduction

Gastroesophageal reflux disease (GERD) is a frequent and challenging adverse event, particularly in patients who underwent sleeve gastrectomy. In addition to worsening patients' quality of life, symptomatic reflux increases the incidence of Barrett esophagus in the population operated on for bariatric surgery [1]. In such population, GERD occurrence is determined by the presence of pre-operative reflux, the surgical technique, and the postoperative excess body weight loss. Indeed, the prevalence of reflux after laparoscopic sleeve gastrectomy (LSG) appears to be higher than for Roux-en-Y gastric bypass (RYGBP) with a de novo reflux rate of 9.8 to 23% for LSG versus 1.7% for RYGBP [2]. However, LSG is the most widely used surgery because of its effectiveness and the lower risk of long-term deficiencies, representing more than 60% of all bariatric surgical procedures.

In case of severe GERD or refractory to PPI, and because of the technical impossibility of performing surgical fundoplication after LSG, some authors recommend conversion to RYGBP. However, this attitude remains controversial, especially if significant weight loss has been achieved. Other teams intended to reduce post-LSG GERD rate either by modifying the procedure, performing the sleeve at distance from the pylorus and with minimal dissection of the hiatus [3], or by associating Nissen fundoplication to the LSG [4]. In the case of persistent reflux after gastric bypass or if the patient refuses further surgery, endoscopic radiofrequency treatment (Stretta®; Mederi Therapeutics, Greenwich, CT, USA) or

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magnetic sphincter augmentation (LINX® Reflux Management System; Torax Medical, Shoreview, MN, USA) has been attempted but there is no current consensus.

Recently, a new endoscopic technique named antireflux mucosectomy (ARMS) has been proposed as a minimally invasive treatment for PPI-refractory GERD [5]. This technique consists of performing a mucosectomy of three-quarters of the circumference at the eso-gastric junction (EJG) in order to reduce the diameter by scarring retraction. This procedure demonstrated promising results in about 70% of patients with GERD in the available series [5–9]. Our team recently published a series evaluating the ARMS technique using band ligation system (ARM-b), with the same outcomes [6]. Here is reported our preliminary experience on 6 patients treated with ARM-b for refractory GERD subsequent to LSG.

Patient and Methods

Patients Selection

We included consecutive patients suffering from post-LSG GERD, refractory to optimized PPI therapy, with a correlation between the symptom and esophageal acid exposure (pH-metry showing a 24-h acid exposure > 6% and a DeMeester Score > 15), and with a high-resolution manometry showing no major esophageal motility disorder according to the Chicago classification. Patients were excluded in the presence of a hiatal hernia > 2 cm or a grade C or D esophagitis. All of them already underwent or had refused a conversion towards RYGBP, and the therapeutic decision was validated during a multidisciplinary obesity meeting. They were proposed to undergo ARM-b being clearly informed about the benefits and risks related to the procedure and informed consent was obtained from all individual participants included in the study.

Procedure

ARM-b procedures were performed under general anesthesia with tracheal intubation. Patients were placed in a supine position. A large operating channel endoscope (3.8 mm) was used for the procedure (Fujinon, Tokyo, Japan or Pentax, Tokyo, Japan), with a multi-band ligation device (Duette, Cook Medical, Winston Salem, USA) placed at the tip of an endoscope. The endoscope was positioned at the level of EGJ within the axis of the lesser curve. Then, the procedure was as follows:

1. A 23-G needle was used to inject in the submucosa adrenaline serum (1/1000) for mucosal lifting.
2. The EGJ mucosa was captured with band ligation (1 cm in the esophagus and 2 cm in the stomach).
3. The captured mucosa was cut with a hexagonal snare (Duette, Cook Medical, Winston Salem, NC, USA). The electrosurgical unit setting was Endocut Q, effect 2 (Erbe, Erlangen, Germany).

These three steps were repeated until completion of a piecemeal mucosectomy of three-quarters of the circumference, involving predominantly the gastric side of the EG junction (see Fig. 1).

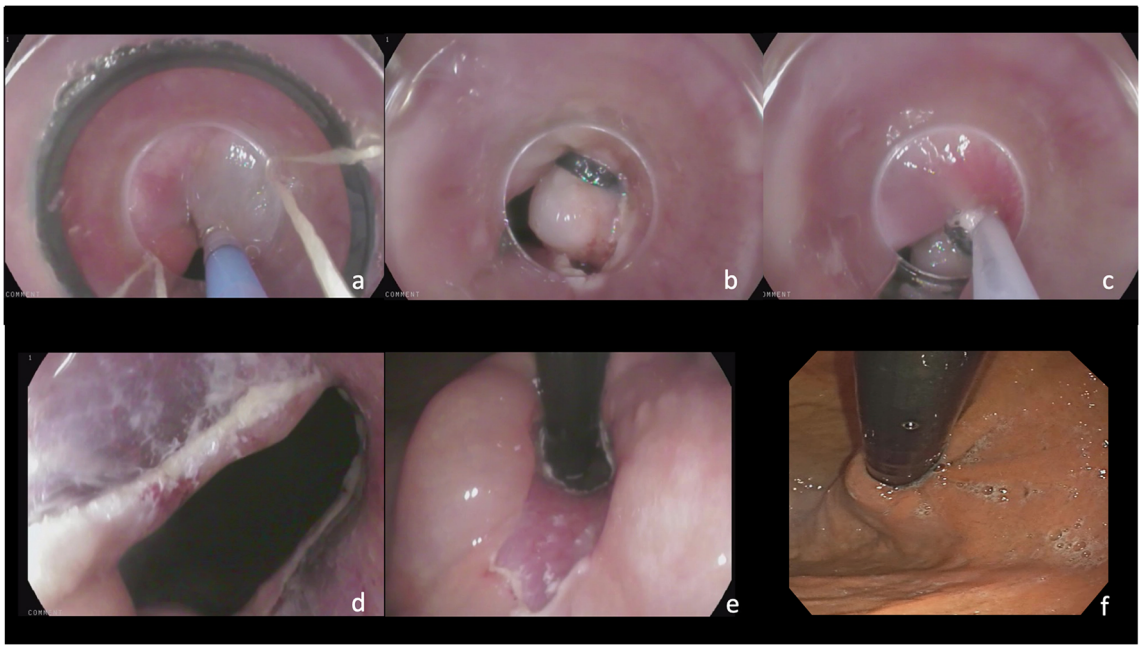

Fig. 1 **a** Submucosal injection. **b** Band ligation. **c** Mucoesctomy under the rubber. **d** Front view of the mucosectomy of the cardia. **e** Retroflexion view of the mucosectomy of the cardia. **f** Result at 3 months (retroflexion)

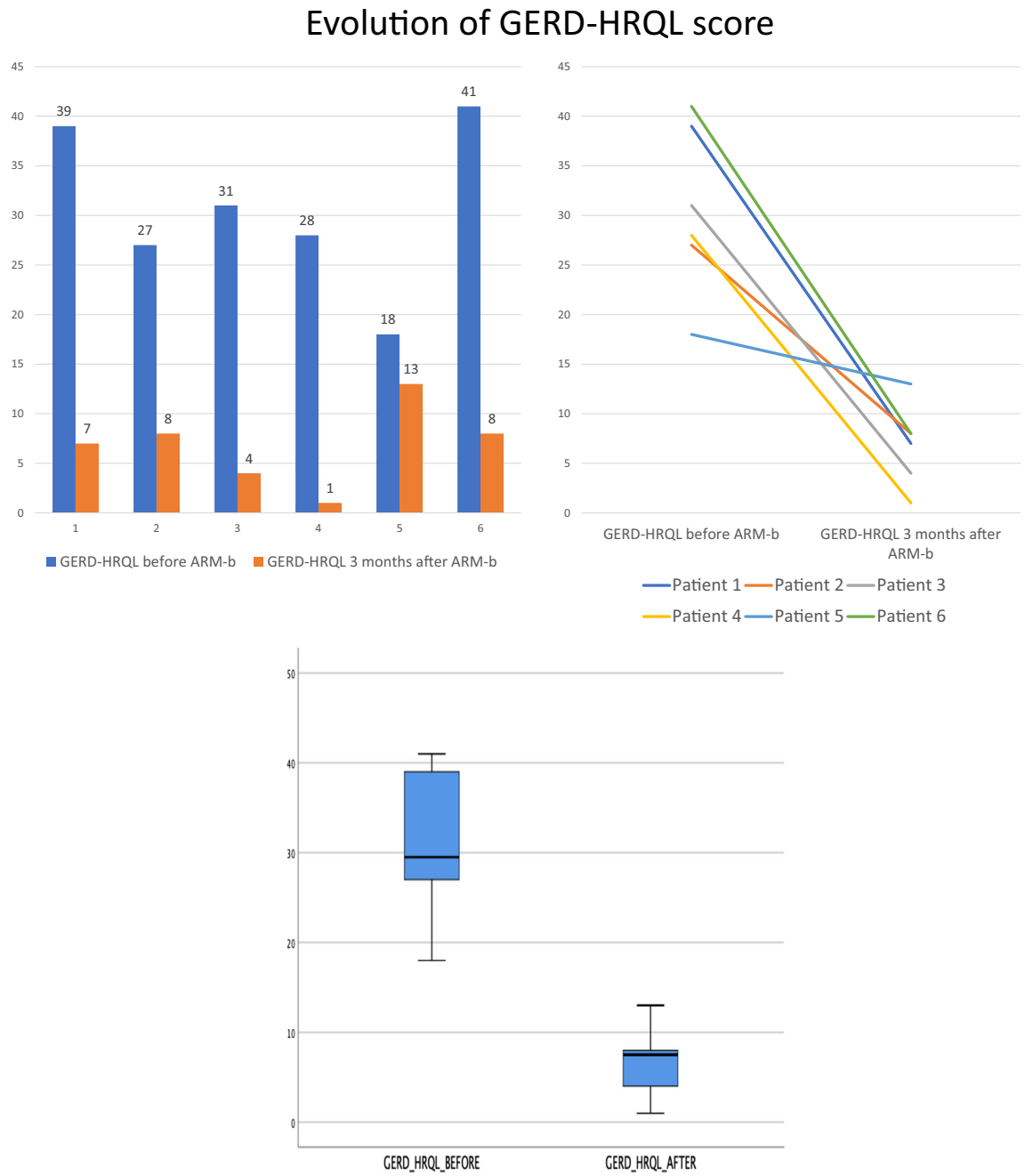

Fig. 2 Evolution of the GERD-HRQL score

After retrieving the distal cap, an endoscopic assessment of the resected area was conducted to treat potential bleeding. Finally, retroflexion was carried out to visualize the resection area on the gastric side. Technical success was defined by the ability to complete a mucosectomy of three-quarters of the EGJ circumference, which was visible in direct vision and retroflexion. All procedures were performed by two experienced endoscopists in esophageal mucosal resections. During the procedure, a class 1 painkiller protocol (paracetamol 1 g), and antiemetic agent (metoclopramide) and a PPI (esomeprazole 40 mg × 2 or lansoprazole 30 mg × 2) were administrated intravenously.

In the absence of an adverse event, the patients were discharged after recovering from the anesthesia, with a prescription of PPIs for 2 months.

Follow-up and Objectives

Patients answered three questionnaires before and 3 months after the procedure: GERDQ, GERD-HRQL, and SF-12 score. All of the immediate or delayed adverse events were registered during follow-up (perforation, bleeding, stenosis,

pain, etc.). A follow-up pH-metry was planned only if GERD symptoms persisted.

The main objective was the efficacy of the procedure on reflux symptoms defined by a 50% or greater decrease in the GERD-Health related Quality of Life (GERD-HRQL) score at 3 months.

The secondary objectives were as follows: the feasibility, the evolution of patients' quality of life (assessed by SF-12 score), the changes in PPI intake, the overall satisfaction before/after ARM-b procedure, and safety of the procedure.

Results

Six patients were included in our recruitment period, 5 women and 1 man aged between 29 and 51 years old. Four of them had refused surgical conversion after LSG, and two underwent RYGBP without GERD symptoms improvement (i.e., 4LSG and 2RYGB after LSG at the inclusion). All patients had a 24 h esophageal pH-monitoring showing significant acid exposition (> 6%) with a significant symptomatic correlation. The mean pre-operative GERD-HRQL score was 30.6 and all patients were taking full-dose PPI use or greater.

The procedure was technically successful in all the cases with a procedure duration lower than 40 min in every case. Clinical success was achieved for five patients, whereas one had a failure. The average follow-up was 5.6 months. The mean GERD-HRQL score at 3 months was 6.8 with a mean decreasing of 74%: 30.67 versus 6.83 $p = 0.003$ (Wilcoxon test, SD = 10.477) (see Fig. 2). In the meantime, three patients continued PPI therapy at the same dose, two patients reduced their consumption by a 3-fold rate, and one patient completely discontinued. The details for each patient are presented in Table 1.

Regarding the adverse events, one patient had an esophageal stricture treated endoscopically by one single dilation session (hydraulic balloon, inflated at 13.5 mm) 2 weeks later and one patient had upper GI bleeding with 2 g/dL of hemoglobin loss managed conservatively with iron perfusion and PPIs.

Table 1 Results

	Patient no.	1	2	3	4	5	6
Baseline	Sex	Female	Male	Female	Female	Female	Female
	Age	48	29	51	40	48	48
	Bariatric intervention	RYGPB	RYGPB	LSG	LSG	LSG	LSG
Scores before ARM-b	PPI dose before ARM-b	Esomeprazole 40 mg daily	Esomeprazole 60 mg daily	Lansoprazole 45 mg daily	Pantoprazole 40 mg daily	Lansoprazole 60 mg daily	Esomeprazole 40 mg daily
	GERDQ before ARM-b	12	14	14	13	15	12
	GERD-HRQL before ARM-b	39	27	31	28	18	41
	Satisfaction related to GERD before ARM-b	Unsatisfactory	Unsatisfactory	Unsatisfactory	Unsatisfactory	Neutral	Unsatisfactory
	SF-12 (Physical Score PCS-12) before ARM-b	27	37	39	31	41	30
	SF-12 (Mental Score MCS-12) before ARM-b	27	47	43	23	44	17
Scores 3 months after ARM-b	PPI dose 3 months after ARM-b (% change)	Esomeprazole 40 mg daily (0%)	Esomeprazole 20 mg daily (− 67%)	Lansoprazole 15 mg daily (− 67%)	No PPI (STOP PPI)	Lansoprazole 60 mg daily (0%)	Esomeprazole 40 mg daily (0%)
	GERDQ 3 months after ARM-b	4 (− 67%)	5 (− 64%)	3 (− 79%)	4 (− 69%)	15 (0%)	6 (− 50%)
	GERD-HRQL 3 months after ARM-b	7 (− 82%)	8 (− 70%)	4 (− 87%)	1 (− 96%)	13 (− 28%)	8 (− 80%)
	Satisfaction 3 months after ARM-b	Satisfactory	Satisfactory	Neutral	Satisfactory	Neutral	Satisfactory
	SF-12 (Physical Score PCS-12) 3 months after ARM-b	44 (+ 63%)	43 (+ 16%)	50 (+ 28%)	46 (+ 48%)	43 (+ 5%)	31 (+ 3%)
	SF-12 (Mental Score MCS-12) 3 months after ARM-b	44 (+ 63%)	53 (+ 13%)	41 (− 5%)	58 (+ 152%)	45 (+ 2%)	41 (+ 141%)

Discussion

The ARM-b is a recently developed endoscopic minimally invasive procedure. This technique shows promising results with clinical success rates ranging from 50 to 69% at 6 months [5–9]. The principle of the procedure is to induce a scarring of the EGJ that creates a relative stricture that restores a mechanical barrier against reflux. The safety profile is also excellent, with a very low risk of delayed bleeding (5%) mostly resolving spontaneously. The most frequent adverse event is post-procedural dysphagia, occurring in 8 to 14% of cases [6, 7], which seems inferior than after antireflux surgery [10]. Also, this dysphagia could be easily addressed by balloon dilation without losing the clinical effect.

Our series shows a 100% rate of feasibility with few adverse events and a relatively high clinical success rate (83.3%) on GERD symptoms, in a specific population of patients with long-standing refractory disease and confirmed acid reflux prior to the procedure. Feasibility of a ¾ circumferential EMR was uncertain before this study because of the fibrosis associated with the LSG. The mean duration of the procedure in patients with LSG was similar to that reported in our series of patients without previous surgery [6]. Therefore, reaching complete technical success was a challenge. Moreover, in our small population, the quality of life after the procedure was significantly improved in half of the cases, with a much-improved mental state thanks to the decreasing of reflux symptoms.

The main advantage of ARM-b in bariatric population is that this procedure is feasible despite the absence of a gastric fundus, particularly after LSG, where a fundoplication is no longer possible. Moreover, in patients that experienced post-LSG severe GERD but with a significant and satisfying weight loss, the technique offers a minimally invasive alternative to RYGBP. Obviously, following strict criteria for patient selection is important, such as persisting GERD under PPIs and the confirmed absence of severe esophageal motility disorder.

These results have to be confirmed in further studies, likely comparative with longer follow-up and a larger population. However, the feasibility of this procedure in the ambulatory setting, with a well-spread technique, as well as the safety profile, makes it a potential serious therapeutic option for managing patients suffering from refractory GERD after LSG and not indicated for RYGBP. Finally, even in the case of failure, surgery remains possible.

Compliance with Ethical Standards

Conflict of Interest Authors MB and JMG had received research grants from the company Boston Scientifics in other areas of research. Authors AD, VV, and LM declare that they have no conflict of interest.

Ethical Approval All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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