



Ineffective Esophageal Motility in Patients with GERD is no Contraindication for Nissen Fundoplication

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Abstract

Background Patients with preoperative ineffective esophageal motility (IEM) are thought to be at increased risk for postoperative dysphagia leading to the recommendations for tailoring or avoiding anti-reflux surgery in these patients. The aim of this study was to evaluate if IEM has an influence on postoperative outcome after laparoscopic Nissen fundoplication (LNF).

Methods Seventy-two consecutive patients with IEM underwent LNF and were case-matched with 72 patients without IEM based on sex, age, BMI, HH size, total pH percentage time, total number of reflux episodes and the presence of BE. Standardized interview assessing postoperative gastrointestinal symptoms, proton pump inhibitor intake, GERD-health-related-quality-of-life (GERD-HRQL), alimentary satisfaction and patients' overall satisfaction was evaluated.

Results Although a higher rate of preoperative dysphagia was observed in patients with IEM (29% IEM vs. 11% no IEM, $p = 0.007$), there was no significant difference in rates of dysphagia postoperatively (2 IEM vs. 1 no IEM, $p = 0.559$). Furthermore, no distinction was found in the postoperative outcome regarding symptom relief, quality of life, gas bloating syndrome, ability to belch and/or vomit or revision surgery between the two groups.

Conclusion Although preoperative IEM has an influence on GERD presentation, it has no effect on postoperative outcome after LNF. IEM should not be a cause for avoiding LNF, as it has been shown as the most effective and safe anti-reflux treatment.

Introduction

Although the prevalence of GERD has been rising since 1995, the rates of anti-reflux surgery have, on the contrary, been declining in the last 9 years [1–3]. Reasons for this phenomenon are the feared long-term side effects of persistent dysphagia and gas bloat syndrome [3–6]. The change in trends of GERD and minimal invasive

innovations in surgery led to more focus on closing the therapy gap between medical and surgical anti-reflux treatment. In an effort to reduce the side-effect rates, while maintaining its efficiency, the gold standard in GERD therapy—the Nissen fundoplication underwent countless modifications, like the partial 270° Toupet fundoplication (TF) and 120° Dor fundoplication (DF) [7–9]. As ineffective esophageal motility (IEM) has shown to pose a risk for postoperative dysphagia, TF was preferred in those patients, due to concerns that a total fundoplication could potentially augment the resistance of the normal outflow [7, 8, 10, 11]. Although the concept of tailoring anti-reflux surgery in patients with IEM has been adopted nearly two decades ago, numerous studies since have shown that the

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Nissen remains superior to partial fundoplication in long-term reflux cessation and does not increase the dysphagia rates in these patients [12–17]. Furthermore, through restoration of the anti-reflux barrier and improvement of the esophagitis, a correction of the esophageal motor function as well as dysphagia could be accomplished [16, 17].

The aim of this study was to analyze the differences in postoperative dysphagia rates, reflux control and degree of overall satisfaction in GERD patients with preoperative diagnosed IEM and those without IEM, who underwent laparoscopic Nissen fundoplication (LNF) in a high-input specialized reflux center.

Materials and methods

Preoperative assessment

All patients received a standardized interview, clinical examination, an upper GI endoscopy and esophageal functioning testing consistent of a manometry and a 24-h-impedance-pH-metry. GERD was diagnosed by positive pH results or increased total reflux episodes with positive symptom correlation on esophageal functioning tests, presence of esophagitis on endoscopy or typical GERD symptoms sensitive to PPI medication. IEM is classified in line with the updated Chicago classification v3.0 calculating the distal contractile integral (DCI) on high-resolution manometry (HRM) [18]. The DCI represents an index of contractile vigor calculated as the product of amplitude, duration and span of the distal esophageal contraction and should have a range of 450–80000 mmHg cm s. An ineffective swallow is characterized by a DCI <450 mmHg s cm. IEM is diagnosed if $\geq 50\%$ of 10 swallows is ineffective.

Surgery

All procedures were performed by the same specialized upper gastrointestinal surgical team. The surgical approach was laparoscopic in all cases. All procedures were standardized regarding surgeon's and patient's positions (anti-Trendelenburg), trocar sites and used instruments. These procedures were accomplished by hiatal dissection and crural closure with 1–5 stitches using non-absorbable sutures. Due to the moderate evidence for the use of an esophageal bougie, as well as the associated risks, all cases were performed without a bougie [19–25].

Nissen fundoplication

LNF was performed in a highly standardized technique as described recently [26]. In brief, both crus of the diaphragm were dissected using the ultrasonic dissector in order to expose the distal esophagus. Special care was taken to achieve an adequate “intraabdominalization” of the lower esophagus of at least 3 cm in length. An extra-short wrap, measuring 1.5 in a maximum with the naked eye was created using 2 close stitches with non-absorbable sutures. Division of the small gastric vessels was avoided when the construction of a tension-free wrap was possible, and special care was taken to complete mobilization of the fundal adhesions to the diaphragm. The first stitch included the anterior esophageal wall. The vagal nerve was always identified and included in the wrap. After the surgery was completed, a blunt laparoscopic instrument was placed through the posterior esophageal wall and the wrap in order to determine the looseness of the fundoplication.

Postoperative care

Postoperative, all patients undergone LNF received a restricted semiliquid food diet for the first 10 days, slowly progressing to solid food in order to avoid dysphagia during the development of mucosal edema. After at least one overnight stay, patients were discharged from the hospital once they showed an unremarkable contrast swallow with diatrizoate on the first postoperative day.

Postoperative assessment

The 72 consecutive patients with IEM and 72 patients without IEM who underwent LNF in our specialized center were included in a comparative analysis. They were matched based on age, sex, preoperative BMI, HH size, preoperative total number of reflux episodes, pH percentage time, presence of Barrett's esophagus (BE) and follow-up time.

The median follow-up time was 5 years. Follow-up was performed by the same physician using a standardized interview assessing postoperative gastrointestinal symptoms, PPI intake and GERD-health-related-quality-of-life (GERD-HRQL). The frequency and severity of postoperative dysphagia were assessed using the classification of Saeed et al. [27], where the ability to swallow can be scored from 0 to 5, where 0 is inability to swallow and 5 is normal swallowing. Adverse effects such as complications, hospital readmission, emergency surgery or elective reoperation were documented.

Statistical analysis

Statistical analysis was performed using SPSS® statistics 20.0 (IBM, Armonk, NY). Data were described using median (interquartile range) or mean (range). Statistical analysis appropriate for nonparametric data was used. Categorical variables were assessed using the Fisher exact test and continuous data using the Wilcoxon rank test as appropriate. Statistical significance was defined as a p value <0.05 .

This study (2293/2017) was approved by the Institutional Review Board of the Medical University of Vienna, Austria.

Results

A total of 652 patients underwent LNF for chronic gastroesophageal reflux disease in a period of 16 years in our specialized upper gastrointestinal surgery center. Seventy-nine ($n = 79$) consecutive patients that presented with IEM according to the Chicago classification v3.0, underwent LNF. Ultimately seven were lost to follow-up, and a total of 72 patients were matched based on sex, age, BMI, HH size, total pH percentage time, total number of reflux episodes, presence of BE and follow-up time with 72 patients without IEM.

The three most common preoperative GERD symptoms in patients with IEM were heartburn (88%), regurgitations (56%) and dysphagia (29%); in contrast to patients with normal motility, heartburn (88%), regurgitations (56%) and respiratory symptoms (19%). We found a significant difference in the preoperative occurrence of dysphagia in

patients between the two groups (29% IEM vs. 11% no IEM, $p = 0.007$) (Table 1).

Outcome

Operative parameters

There was no significant difference in the operation time when comparing the two groups (98 min IEM vs. 69 min no IEM, $p = 0.671$). No intraoperative complications were seen. All patients received a hiataloplasty, whereas in seven patients (5%), a hiatal mesh was implanted additionally (Table 2).

Symptom relief

The median follow-up time was 5 years (IQR, 1.8–10). Heartburn, regurgitations and dysphagia were fully eliminated in ninety-six (76%), sixty (74%) and seventeen (59%) of the patients, respectively, with no significant difference between the two groups. A comparison of the three most reported symptoms before and after LNF is shown in Fig. 1. Eighty-nine (79%) patients reported to be completely free of PPIs postoperatively, while twenty-four (21%) patients needed regular PPI use, with no difference between patients with IEM and those without (11 IEM vs. 13 no IEM, $p = 0.655$).

Side effects

Persistent dysphagia was reported in only three (2%) patients. Rarely difficulties swallowing with solids only was reported by thirty (21%) of the patients, while ten (7%)

Table 1 Demographic data and results of preoperative diagnostics of all patients

	IEM	No IEM	
Total $n = 144$ (100%)	$N = 72$ (50%)	$N = 72$ (50%)	
Sex (M vs. F)	41 versus 31	41 versus 31	$p = 1$
Median age (IQR)	55	55	$p = 0.862$
Median BMI (IQR)	27	27	$p = 0.716$
Median size of HH (cm)	2	2	$p = 0.439$
Median total pH $<4\%$	9.7	7.3	$p = 0.216$
Median total reflux episodes	78	67	$p = 0.562$
Presence of BE	8	7	$p = 0.554$
Use of PPIs	56	57	$p = 0.839$
Symptoms	63	63	$p = 1$
Heartburn	41	41	$p = 1$
Regurgitations	21	8	$p = 0.07$
Dysphagia			

patients had occasional difficulties swallowing with solids (Fig. 2). A whole of 112 (57 IEM vs. 55 no IEM, $p = 0.688$) patients retained their ability to belch/vomit and 15 (6 IEM vs. 9 no IEM, $p = 0.413$) complained about increased daily gas bloating, with no difference between the groups.

Table 2 Intraoperative and perioperative data

	IEM	No IEM	
Median OR duration (min)	97.5	69	$p = 0.671$
Hiatal repair	72	72	$p = 1$
Median blood loss (ml)	0	0	–
Intraoperative complications	0	0	–

Dysphagia

There were a total of twenty-nine (20%) patients who reported preoperative dysphagia. After LNF, seventeen of the patients ($n = 17/29$, 59%) reported a full elimination of dysphagia, while seven ($n = 7/29$, 24%) patients reported rarely difficulties swallowing with solids, four patients ($n = 4/29$, 14%) occasional difficulties swallowing with solids and one patient ($n = 1/29$, 3%) persistent dysphagia (PD). When analyzing new-onset dysphagia, we observed twenty-three patients ($n = 23/115$, 20%) that developed rarely difficulties swallowing with solids, six ($n = 6/115$, 5%) occasional difficulties swallowing with solids and two ($n = 2/115$, 2%) PD. From the total of 31 patients with new-onset dysphagia, eleven (35%) had preoperative IEM, while the rest twenty patients (65%) had no IEM. These findings show there was no increased rate of new-onset dysphagia in patients with preoperative IEM (11 IEM vs. 20 no IEM, $p = 0.068$). There was no significant difference in PD (2 IEM vs. 1 no IEM, $p = 0.559$) between the groups (Table 3). PD was described in one patient where

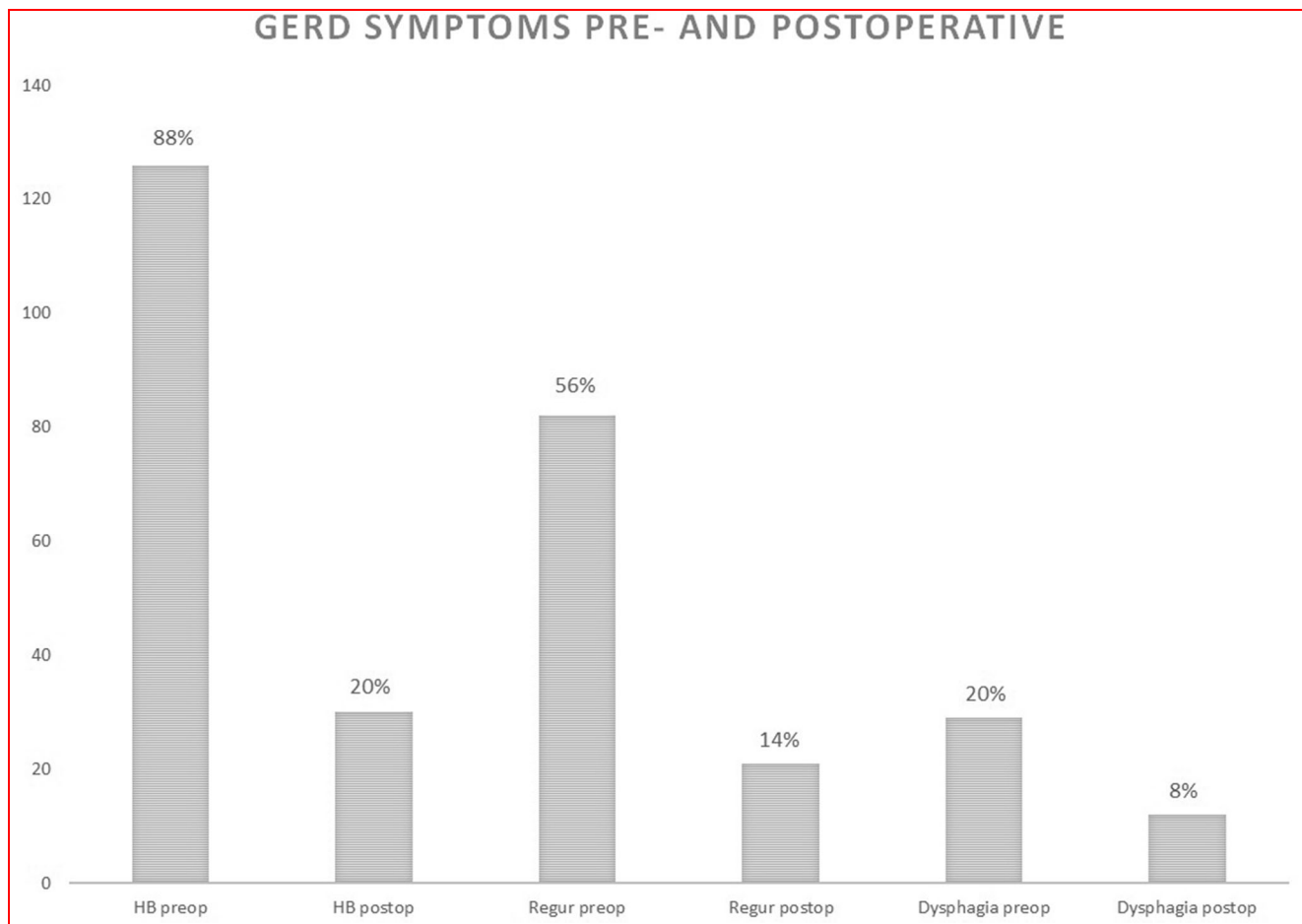
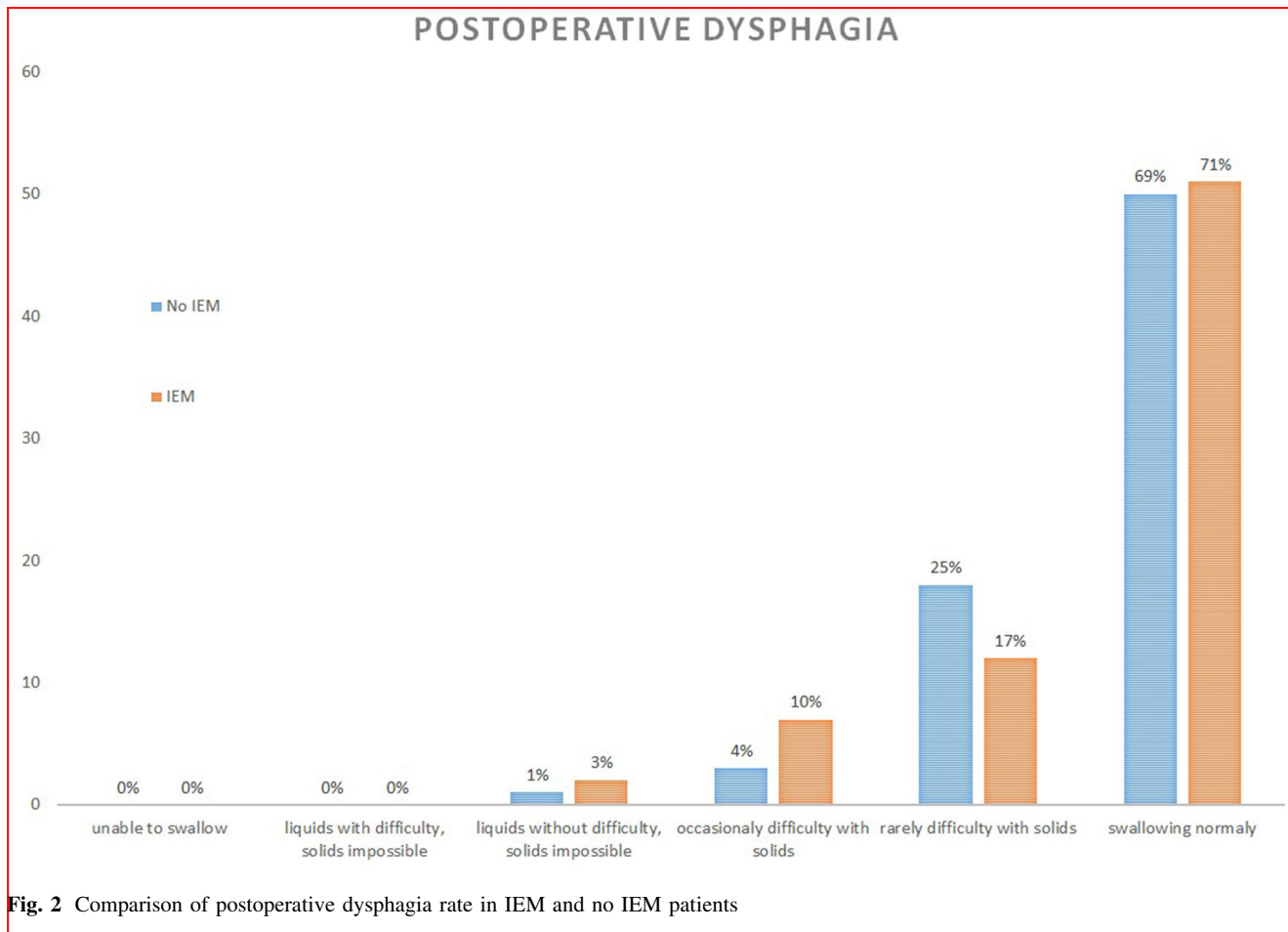


Fig. 1 Comparison of three most common GERD symptoms pre- and postoperative



postoperative diagnostics (barium swallow, real-time MRI and EGD) showed no morphologic abnormalities so that no re-operation was indicated, but multiple Botox injections. Two further patients with PD also showed no abnormalities in the postoperative barium swallow, real-time MRI or even EGD, and no further interventions were done.

Table 3 Postoperative median follow-up of 5 years

	IEM	No IEM	
New-onset dysphagia	11	20	$p = 0.068$
Persistent dysphagia ^a	2	1	$p = 0.559$
Ability to belch/vomit	57	55	$p = 0.688$
Daily gas bloating	6	9	$p = 0.413$
Revision surgery	6	2	$p = 0.145$
Median GERD-HRQL score	2	1	$p = 0.055$
Alimentary satisfaction	9	10	$p = 0.3$

^aPersistent dysphagia was defined as ≤ 2 using the classification of Saeed et al. [20]

Interventions

Endoscopic dilatation was performed in three patients (2%) with postoperative dysphagia, with one of them having a successful outcome (33%). Multiple endoscopic Botox injections were performed in one patient (1.4%) with postoperative dysphagia with no significant resolution. Eight patients (6%) required re-operation. Three (38%) patients due to re-herniation of the wrap: one patient suffered an acute paraesophageal hernia on the 2 postoperative day, one patient developed a re-herniation 6 months after the primary surgery and one patient needed open revision due to occurrence of a type IV hiatal hernia 4 years later. Two patients (25%) due to slipping of the fundus, 6 months and 4 years after the primary surgery, respectively. Two further patients (25%) due to reoccurrence of reflux as well as slipping of the fundus. One of them 10 years after the primary surgery and the other 5 years later, after which he developed dysphagia undergoing multiple endoscopic balloon dilatations, followed by three stent implantations, finally resolving his dysphagia. Lastly, one patient underwent Toupet re-fundoplication due to dysphagia 3 years

later (13%). We found no difference in the rates of reoperation between the two groups (6 IEM vs. 2 no IEM, $p = 0.145$) (Table 3).

Quality of life

The preoperative median GERD-HRQL was 19 (IQR, 14–24). LNF led to a significant reduction in the GERD-HRQL total score (19 (IQR, 14–24) vs. 2 (IQR, 0–5), $p = 0.00$). No difference was found in the postoperative GERD-HRQL score (2 IEM vs. 1 no IEM, $p = 0.055$) or the median alimentary satisfaction (9 IEM vs. 10 no IEM, $p = 0.3$) between the groups (Table 3).

Discussion

Despite the hypothesis that patients with coexisting IEM may have a greater risk for postoperative dysphagia, it still remains controversial if they would benefit more from a partial fundoplication or if esophageal motility itself has an influence on postoperative outcome at all [8, 10, 12–15, 28, 29]. Moreover, esophageal motility has shown to improve after LNF either through mucosal healing with reflux control or increased outflow resistance by augmenting the gastroesophageal junction [17]. As LNF remains superior to partial fundoplication in long-term reflux control, the tailored anti-reflux concept in IEM patients' should be reconsidered.

In our study we aimed to compare long-term postoperative outcomes after LNF between patients with preoperative IEM and those with regular motility. Up to date, no study has been published with a long-term follow-up of up to 14 years and a greater case-matched sample size of patients with IEM based on the Chicago classification v3.0 and diagnosed with HRM.

When analyzing the preoperative GERD presentations—the three most common symptoms differed between the groups. Patients with IEM presented with heartburn (79%), regurgitations (61%) and dysphagia (33%), in contrast to patients with normal motility who presented more commonly with respiratory symptoms (16%), rather than dysphagia. The significant difference in preoperative dysphagia rates between the groups (33% IEM vs. 15% no IEM, $p = 0.06$) is not surprising, supporting previous evidence that esophageal motility influences symptoms of the disease [13]. This may be one of the reasons why the choice of fundoplication is occasionally still made according to the presence of IEM. Furthermore, when comparing the elimination of the symptoms, preoperative esophageal motility had no effect on the postoperative rates of heartburn (18 IEM vs. 12 no IEM, $p = 0.218$), regurgitations (13 IEM vs. 8 no IEM, $p = 0.266$), dysphagia (2

IEM vs. 1 no IEM, $p = 0.559$) or postoperative PPI use (11 IEM vs. 13 no IEM, $p = 0.655$). These findings are coinciding with foregoing data that IEM has no influence on postoperative outcome after LNF [12, 13, 15, 30].

The opinion that patients with preoperative IEM have an increased risk of postoperative dysphagia led to recommendations for tailoring or even avoiding anti-reflux surgery in these patients. In order to reduce the perceived likelihood of this feared side effect, many prefer the Toupet over the Nissen fundoplication, even though to date no prospective data exist to encourage such practice [30–33]. In our study, we observed a total of three patients with PD with solids and liquids (2%) at time of follow-up. This is in concordance with our prior findings when analyzing 350 patients after LNF at our institution and considerably lower than described in the previous literature ranging from 4 to 11% [26, 34, 35]. Moreover, as mentioned above, when comparing patients with IEM and those without IEM, we found no significant difference in the postoperative PD rate (2 IEM vs. 1 no IEM, $p = 0.559$) or in the rate of new-onset dysphagia (11 IEM vs. 20 no IEM, $p = 0.068$), confirming the results of the previous literature showing that esophageal motility has no effect on the postoperative occurrence of dysphagia after fundoplication [12, 13, 15]. Furthermore, these findings show that when performed in a specialized high-output reflux center, in a highly standardized technique, the long-term postoperative dysphagia rates after LNF are low. Additionally, the elimination of pathological reflux and restoration of the anatomy possibly results in improvement of esophageal motility, and thus dysphagia itself. When analyzing further possible adverse effects of the LNF such as gas bloat syndrome (6 IEM vs. 9 no IEM, $p = 0.413$) and the inability to belch and/or vomit (57 IEM vs. 55 no IEM, $p = 0.688$), no difference was observed in the outcome between the groups, in concordance with earlier evidence [13].

In the small subset of patients that do develop side effects like persistent dysphagia or recurrence of GERD symptoms, interventions like endoscopic balloon-dilatation or revision fundoplication are still possible treatment options. In our series, we had three patients who underwent endoscopic dilatation due to dysphagia, on the lower end when compared to several studies [36, 37]. Eight patients underwent revision surgery, mostly due to re-herniation of the wrap as well as GERD reoccurrence and slipping of the fundus with no difference between the two groups (6 IEM vs. 2 no IEM, $p = 0.145$). These finding were not unpredicted as the incidence of 2–6% has been commonly described, increasing with the time of follow-up [13, 15].

Lastly, our results showed a significant decrease in the GERD-HRQL total score (19 (IQR, 14–24) vs. 2 (IQR, 0–5), $p = 0.00$) after LNF, proving a substantial increase in quality of life and confirming previous outcomes [38, 39].

Certain limitations of our study, like its retrospective nature, as well as a lack of objective (EFTs) postoperative assessment of GERD and preoperative dysphagia elimination should be taken into consideration. A prospective randomized clinical trial is currently being initiated in order to bring evidence to a higher level and resolve the contraversion about tailoring LNF in patients with IEM.

Conclusion

Our findings showed that although IEM diagnosed in preoperative HRM affects the clinical symptoms of GERD, it does not affect the outcome of LNF. LNF is a safe and effective surgical procedure with low postoperative morbidity rates and efficient symptom relief not only in patients with normal esophageal motility but also in those with IEM.

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