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Intraoperative endomanometric laparoscopic Nissen fundoplication improves postoperative outcomes in large sliding hiatus hernia with severe gastroesophageal reflux disease.

A retrospective cohort study.

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- Laparoscopic Nissen fundoplication for GERD may be followed by recurrent symptoms or the appearance of dysphagia that may be persistent that affect patient satisfaction.
- .use of the intraoperative endoscope and intraoperative manometry improves postoperative outcomes
- no redo surgery in endomanometric LNF

Intraoperative endomanometric laparoscopic Nissen fundoplication improves postoperative outcomes in large sliding hiatus hernia with severe gastroesophageal reflux disease. A retrospective cohort study.

Graphical abstract

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ABSTRACT

Background: Laparoscopic Nissen Fundoplication (LNF) is the gold standard surgical intervention for gastroesophageal reflux disease (GERD). LNF can be followed by recurrent symptoms or complications affecting patient satisfaction. The aim of this study is to assess the value of the intraoperative endomanometric evaluation of esophagogastric competence and pressure combined with LNF in patients with large sliding hiatus hernia (> 5cm) with severe GERD (DeMeester score >100).

Materials and Methods: This is a retrospective, multicenter cohort study. Baseline characteristics, postoperative dysphagia and gas bloat syndrome, recurrent symptoms, and satisfaction were collected from a prospectively maintained database. Outcomes analyzed included recurrent reflux symptoms, postoperative side effects, and satisfaction with surgery.

Results: 360 patients were stratified into endomanometric LNF (180 patients, LNF+) and LNF alone (180 patients, LNF). Recurrent heartburn (3.9% vs. 8.3%) and recurrent regurgitation (2.2% vs. 5%) showed a lower incidence in the LNF+ group (p=0.012). Postoperative score III recurrent heartburn and score III regurgitations occurred in 0% vs. 3.3% and 0% vs. 2.8% cases in the LNF+ and LNF groups, respectively (p=0.005). Postoperative persistent dysphagia and gas bloat syndrome occurred in 1.75% vs. 5.6% and 0% vs. 3.9% of patients (p=0.001). Score III postoperative persistent dysphagia was 0% vs. 2.8% in the two groups (p=0.007). There was no redo surgery for dysphagia after LNF+. Patient satisfaction at the end of the study was 93.3% vs. 86.7% in both cohorts, respectively (p=0.05).

Conclusions: Intraoperative high-resolution manometry (HRM) and endoscopic were feasible in all patients, and the outcomes were favorable from an effectiveness and safety standpoint.

Keywords: Antireflux surgery, Fundoplication, Gastroesophageal reflux disease, High-resolution Manometry, Lower esophageal sphincter.

Introduction

Gastroesophageal reflux disease (GERD), caused by the reflux of gastric acid into the esophagus, affects up to 33% of the adult population [1]. Worldwide, the prevalence of GERD has been rising [2]. The pathophysiology of GERD is multifactorial. GERD is accompanied by heartburn (HB), regurgitation, erosive esophagitis, esophageal strictures, Barrett esophagus, or extra-esophageal symptoms that negatively impact the quality of life. Complete workup for diagnosing GERD, including high-resolution manometry (HRM), pH monitoring, and endoscopy, is mandatory [3]. Three ways to treat GERD are lifestyle changes, medication therapy, and surgical intervention. Medical treatment with proton pump inhibitors (PPI) often requires lifelong medication. Moreover, compliance with long-term therapy is complex, and half of the patients have persistent symptoms during medical treatments. Antireflux surgery creates a mechanical barrier that prevents acid reflux from entering the esophagus, as opposed to PPI, which reduces the acidity of the reflux [4]. The effects of implantation surgery for GERD are not well proven [5-9]. To date, the most often used antireflux procedure is laparoscopic Nissen fundoplication (LNF). LNF is highly effective in controlling reflux over time, reducing GERD symptoms while maintaining an acceptable risk profile [10]. Despite a tailored approach, LNF is not without risks of adverse effects, such as fundoplication disruption, persistent dysphagia (PD), gas-bloat syndrome, and recurrence of GERD, which sometimes require endoscopic dilatation or reoperation [11]. These problems have a negative impact on patient's satisfaction and quality of life [12]. Previous research reported intraoperative manometry and endoscopy to improve results [13]. There is currently a lack of studies that evaluate the role of intraoperative endomanometric assessment during LNF as an appropriate surgical option for the management of patients with large hiatus hernias (HH) (>

5cm) and severe GERD (DeMeester score >100) for reducing long-term postoperative recurrent symptoms and side effects and improving patient satisfaction.

Materials and methods

Study design and eligibility criteria

A retrospective cohort multicenter study was conducted in the surgical units of our Universities' Hospitals on 360 patients who underwent LNF for a clinical diagnosis of large sliding hiatus hernia (> 5 cm) [14] with severe GERD (Demeester score >100) between April 2012 and April 2020. We expect greater failure of the natural anti-reflux mechanism and that's why the use of this new technique. Our previous experience showed significant recurrence of the symptoms and increased postoperative use of PPI medications in patients with severe reflux defined above. **Patients were stratified into endomanometric LNF (180 patients, LNF+) and LNF alone (180 patients, LNF). From 2012 to 2014, LNF alone was the preferred procedure. Intraoperative endomanometric laparoscopic Nissen fundoplication (LNF+Endomanometry) replaced LNF from 2014 to 2020.** This largely based on surgeon's preferences driven by good experience and results of adopting intraoperative HRM. Patients included in the study met standard indications for GERD surgery [15]. They were adult patients ≥18 years with large sliding hiatus hernia (> 5 cm) and severe GERD (DeMeester score >100) with typical symptoms and unsuccessful medical management or patients with unresponsive or inadequate symptom control despite adequate medical therapy with or without extra-esophageal atypical symptoms related to GERD (cough, globus, or hoarseness). Patients had a confirmed diagnosis of the hypotensive lower esophageal sphincter assessed by HRM and a positive pH/impedance test (based on DeMeester scores). Moreover, they were fit and consented to surgery. Every patient in this study completed a three-year follow-up period. We excluded pregnant patients, those who were unfit for surgery (severe cardiac, respiratory, renal diseases, and bleeding disorders),

non-cooperative patients, patients lost to regular follow-up, patients who had undergone previous antireflux surgery or who required a concurrent abdominal procedure at the same time as fundoplication (e.g., cholecystectomy). Moreover, patients were excluded if they had any of the following conditions: psychiatric disorders, esophageal dysmotility, progressive systemic sclerosis, GERD secondary to scleroderma, bile reflux, complications related to GERD (stricture, short esophagus, Barrett esophagus, adenocarcinoma), dense upper abdominal adhesions and technical difficulties with esophageal dissection due to periesophagitis, symptoms consistent with gastroparesis or delayed gastric emptying (diagnosed by nuclear medicine gastric emptying studies), previous gastric and esophageal surgery, helicobacter pylori infection, co-existent conditions like peptic ulcer disease or cholelithiasis as causes of GERD-like symptoms, previous surgery for achalasia, previous radiotherapy to the upper abdomen, pyloric stenosis, cases that developed intraoperative complication or postoperative complications related to the procedure and required conversion (splenic injury) or reintervention (bleeding) or pneumothorax and absence of preoperative investigations. Based on the surgical technique, patients were divided into endomanometric LNF (LNF+) and LNF alone (LNF). The study was conducted under a standard protocol and approved by Ethics Committee and registered in clinical trial. The study was conducted according to the principles of the Helsinki Declaration. This study has been reported per the STROCSS criteria [16].

Outcomes definition and measurement

Primary outcomes were recurrent postoperative symptoms [recurrent HB, regurgitation, atypical symptoms] or postoperative complications (PD and gas bloat syndrome). The secondary outcome was postoperative patient satisfaction. Barium meal study (Figure 1), endoscopy, or HRM were used to diagnose hiatal hernia (HH). Heartburn, acid regurgitation, and atypical symptoms were defined according to a previous publication [17]. A modified

DeMeester scoring system was used to evaluate the typical symptoms, including HB, regurgitation, and dysphagia [18]. The word "recurrent" was used when symptoms persist following LNF. The emergence of symptoms or clinical complications that did not exist before LNF was regarded as a "complication" [19]. DeMeester 24-hour pH scoring was performed on patients who had been off acid suppression treatment. The value for the DeMeester composite score is DMS <14.72 (no GERD), DMS 14.72-50 (mild GERD), DMS 51-100 (moderate GERD), and DMS >100 (severe GERD) [20]. As previously described, HRM was performed for all patients within three days of the operation [21]. **The standard lower esophageal sphincter (LES) resting pressure is about 15-20 mmHg. We evaluated the intraoperative LES pressure following wrap formation to determine the pressure value of the new high-pressure zone (HPZ). The intraoperative targeted LES pressure values ranged between 20 and 40 mmHg. If the new HPZ does not match the expected values, the pressure is changed by altering the fundoplication**. If the intraoperative recording indicated lower-than-expected values, the wrap was tightened by inserting stitches (typically one or two). In the case of high-pressure values, we removed one or two sutures and rebuilt thefundoplication without tension. No cases required complete redo wrapformation. An Olympus video endoscope was used for the endoscopic examination. Following wrap fixation, the anatomic aspects of the antireflux valve were classified according to Seltman and Jobe's classification for the definition of a "normal endoscopic anatomy after successful fundoplication (based on the following findings: tight adherence to scope, cardia circumferences < 35 mm, no cardial dilatation, valve length (body) 3 to 4 cm, nipple or coil type, intra-abdominal location, and proper repair position [22]. The Los Angeles classification of esophagitis grading system was employed, with Grades A, B, C, and D to grade the severity [23]. A hernia size > 5 cm was defined as a large hiatal hernia [24]. We also included

two "yes or no" questions to gauge satisfaction with the outcome: “Were you satisfied or dissatisfied with surgery?”

Operative technique

The anesthesia protocol was the same for all patients: oral flunitrazepam as premedication, etomidate and fentanyl induction, isoflurane and fentanyl maintenance, and atracurium. Preoperative antibiotic prophylaxis was given. In brief, the patient is positioned in a lithotomy position with legs abducted. We used five trocars and a harmonic scalpel throughout the surgery. The first step of the operation is the reduction of the herniated stomach, the excision of the hernia sac, and the mobilization of at least a 3 cm tension-free intra-abdominal esophagus (Figure 2). Both vagal nerves are carefully preserved. Posterior cruroplasty is regularly performed with 2-3 non-absorbable, interrupted sutures. A "U"-shaped mesh made of fenestrated PTFE (Low profile bioresorbable coated permanent mesh, Ventralight ST, registered trademark of C.R. Bard. Inc. or an affiliate, REF; 5954113) is fixed to both crura with two non-absorbable sutures or by titanium tacker. LNF is performed on all patients using the conventional method. Two or three non-absorbable sutures are used to create a 360-degree posterior wrap of the fundus that is about 2 cm in length [25]**. Intraoperative HRM and endoscopy were performed only for the endomanometric LNF group following wrap formation.**

Discharge and postoperative follow-up evaluation

When patients are symptom-free, they are discharged from the hospital. They are assigned to the outpatient department (OPD) for in-person, telephone, or email follow-up appointments. During OPD visits, the majority of patients are clinically evaluated for recurrent symptoms or the occurrence of complications. Patients who experienced recurrent symptoms or PD during their OPD visits were investigated with upper gastrointestinal endoscopy, HRM, and a barium esophagogram. According to our hospital's current standard of care, patients are followed up

at six months, one year, two years, and three years after surgery. Patients were made aware of transient dysphagia in the first six months due to edema and esophageal ileus. Extra-oesophageal symptoms may not improve immediately, and new symptoms, such as gas bloating, may occur after surgery.

All patients in this study had been followed up for at least three years. One year following surgery, and then once a year after that, a postoperative endoscopy was performed. At the end of the study, all patients were contacted by telephone or email and asked if they were satisfied or dissatisfied with their surgery.

Statistical analysis

Statistics and data administration were handled with SPSS version 28 (IBM, Armonk, NY, USA). We used the Kolmogorov-Smirnov test and direct data visualization techniques to check the distribution of our numerical data and ensure their normal or non-normal distribution. Means and standard deviations or medians and ranges were calculated from quantitative data under the assumption of normality. Numbers and percentages were used to summarize the categorical data. The independent t-test or the Mann-Whitney U test was used to compare quantitative data between the study groups when the variables in question were normally distributed or not normally distributed, respectively. The Chi-square or Fisher's exact tests were used to compare categorical data. All statistical tests were two-sided. P values < 0.05 indicated statistical significance.

Results

Baseline characteristics

Figure 3 shows the flowchart of inclusion and exclusion criteria. Demographics and baseline characteristics details are summarized in Table 1. The two study groups included 126 females (70%) and 137 (76.1%), respectively (p=0.192). At the preoperative upper GI endoscopy, we observed grade A (3.9% vs. 5.6%), grade B (4.4% vs. 8.9%), grade C (63.9% vs. 62.8%), and

grade D (27.8% vs. 22.8%) esophagitis, in the LNF+ and LNF groups, respectively (p=0.087). Preoperative initial symptoms were HB (79.4% vs. 69.4%), regurgitation (15.6% vs. 25.6%), and atypical symptoms (5% vs 5%) (p=0.061). Modified DeMeester scores of the severity of initial symptoms were score I HB (11.1% vs. 10%), score II HB (15% vs. 10.6%), score III HB (53.3% vs. 48.9%), a score I regurgitation (0.6% vs. 3.9%), score II regurgitations (5% vs. 6.1%) and score III regurgitations (10% vs 15.6%) (p=0.634). Atypical symptoms occurred in 9 patients in each group (5%).

Intraoperative outcomes

Intraoperative findings are shown in Table 2. All surgeries were performed laparoscopically without any intraoperative complications. Operative time was significantly longer in the LNF+ (112.3±7.2 min vs. 59.3±6.05 min; $p < 0.001$). Intraoperative HRM and endoscopy were performed, with procedure-related complications occurring in 5 patients (2.8%) in the LNF+ group: esophageal wall bleeding was reported in three patients (1.7%) and epistaxis in two patients (1.1%). The mean time to perform intraoperative HRM and endoscopy was 20.29±4.17 and 21.16±4.33 minutes, respectively.

pH and HRM monitoring

The comparison between pre-, intra-, and postoperative pH monitoring and HRM data is summarized in Table 3. Preoperative LES pressure was statistically lower in the LNF+ group (6.04±2.1 vs. 6.8±2.4 mmHg, P=0.001); the mean intraoperative LES pressure was 32.5±4.6 mmHg in the LNF+ group. At the end of the study, LES pressure was significantly higher in the LNF+ group (19.17± 0.38 and 14.55±1.5 mmHg, $p< 0.001$). HRM metrics before and at the end of the study showed that mean LES pressures significantly increased after surgery from 6.04±2.1 mmHg to 19.17± 0.38 mmHg in LNF+ and 6.8±2.4 mmHg to 14.55±1.5 mmHg in LNF alone patients. DeMeester pH monitoring metrics before and at the end of the

study showed that the total DeMeester score value in the LNF+ group was statistically higher in the preoperative study period ($p < 0.001$) and significantly lower at the end of the study period ($p < 0.001$) compared with the LNF alone group. The median DeMeester pH score was 119.1 vs. 113.13 preoperatively and 11.5 vs. 13.34 postoperatively.

Postoperative outcomes

The postoperative outcomes of the two study groups are summarized in Table 4 and Figure 4. A statistically significant difference favoring the LNF+ group regarding the postoperative discontinuation of PPIs (1.7% vs. 7.2%; $p= 0.011$), HH recurrence after surgery (1.7% vs. 5.6%; $p= 0.048$), postoperative esophagitis grading A (0% vs. 5.6%; $p= 0.001$), postoperative recurrent symptoms ($p= 0.012$), the appearance of new complications ($p= 0.001$), treatment of recurrent symptoms or complications ($p < 0.001$), indication for redo surgery ($p < 0.001$), DeMeester score of severity of recurrent symptoms ($p= 0.005$), postoperative dysphagia score ($p= 0.007$), GERD recurrence and severity ($p= 0.001$), and patient satisfaction ($p= 0.005$) was found, favoring the LNF+ group. HB was resolved in 136 patients (75.6%) and 110 patients (61.1%) but recurred in seven patients (3.9%) and 15 patients (8.3%) in the two groups, respectively. Regurgitation resolved in 24 (13.3%) and 37 patients (20.6%) but recurred in four (2.2%) and nine patients (5%), respectively. No recurrence of atypical symptoms in the two groups was reported. DeMeester score of severity of recurrent symptoms showed score I HB recurrence (2.8% vs. 3.9%), score II HB recurrence (1.1% vs. 1.1%), score III HB recurrence (0% vs. 3.3%), a score I regurgitation recurrence (2.2% vs. 0.6%), score II regurgitation recurrence (0% vs. 1.7%) and score III regurgitation recurrence (0% vs 2.8%). Postoperative dysphagia developed in 3 (1.7%) and 10 (5.6%) patients in the two groups. Gas bloat syndrome occurred in 7 patients (3.9%) for LNF alone, whereas no cases were reported in the LNF+ group. Regarding postoperative PD, three patients in the LNF+ group were in the

score I permanent PD. In contrast, five patients (2.8%) who developed PD in the LNF alone group had a score of II dysphagia, and five (2.8%) had a score of III dysphagia. A single session of endoscopic dilatation treated all cases with PD in the LNF+ group. Patients with PD in the LNF alone group were treated with two sessions of endoscopic dilatation (2 patients), three sessions of endoscopic dilatation (one patient), and four sessions of endoscopic dilatation (two patients). Five patients with score III dysphagia underwent redo surgery. No mortality was recorded. No GERD recurrence was reported in 169 and 156 patients in the two groups. Mild GERD was the most typical form in the LNF+ group, while severe recurrent GERD was the most common form in LNF alone. Moreover, 168 patients (93.3%) and 156 patients (86.7%) were satisfied in the two groups at the end of the study.

Discussion

The ultimate goal of LNF is to increase GERD patients' satisfaction by controlling reflux symptoms and reducing reflux-related complications. Postoperative complications following LNF for GERD can include PD, recurrent HB, regurgitation, and atypical symptoms, all of which can have a negative impact on quality of life. Various attempts have been made to reduce postoperative complications and improve patient satisfaction but with conflicting results [26]. To our knowledge, no study has employed intraoperative HRM and Endoscope to improve surgery results and patient satisfaction in patients with giant sliding HH (> 5cm) and severe GERD (DeMeester score > 100). We found that patients who had endomanometry at the time of LNF significantly improved postoperative symptoms (HB, regurgitation, atypical symptoms), fewer postoperative complications (PD and gas bloat syndrome), and higher patient satisfaction after surgery compared with patients who underwent LNF alone. Patients with HH have reflux episodes, greater esophageal acid exposure, and more severe esophagitis on endoscopy than those without this condition [27]. Since its advent, mini-invasive

laparoscopic surgery has revolutionized the surgical management of GERD, steadily increasing the number of antireflux procedures performed. LNF significantly improves HB, regurgitation, and atypical symptoms [28]. Endomanometric LNF and LNF alone significantly improved the LES pressure at the end of our research; however, the improvement was more significant after endomanometric LNF. There is uncertainty over how much LES pressure could prevent postoperative recurrent reflux while preventing dysphagia. We found statistical differences among patients whose preoperative initial symptoms persisted compared to those where they resolved. Based on our experience, an intraoperative LES pressure of 20-40 mmHg is sufficient to maintain the mean LES pressure at 19 mmHg at the end of the follow-up period. Such pressure of the LES is sufficient to control reflux. It appears sufficient to prevent the excessive rise of LES pressure, which frequently leads to incomplete relaxation of the LES, resulting in high esophageal outflow resistance and further PD [29]. Acute-onset dysphagia affects approximately 50% of patients and is due to edema and inflammation caused by surgery and usually disappears within three months with conservative treatment [30]. Persistent dysphagia can be caused by various factors, including the creation of a tight, slipped, or displaced fundoplication, preoperative esophageal motility disorders [31], and diaphragmatic hiatus stenosis after antireflux surgery [32]. When dysphagia becomes persistent, as it does in up to 35% of patients, it significantly influences the patient's quality of life and is a complex problem to manage [33]. Endomanometric LNF aims to create a wrap around the lower esophagus, induces an adequate LES pressure, and restores normal anatomy at the esophagogastric junction, reducing the incidence and severity of postoperative recurrence of symptoms and complications that may require redo surgery [34]. Several studies examined the relationship between preoperative pH, manometry, and the development of postoperative dysphagia, but no definitive results were found [35]. We employed intraoperative HRM to restore LES to normal after surgery. Postoperative elevated

LES pressures were associated with prolonged dysphagia, likely due to the 'tightness' of the fundoplication [36]. The use of endomanometric LNF might be time-consuming. The most difficult operating phase in our experience with endomanometric LNF is the intraoperative HRM to ensure LES pressure. Higher LES pressure necessitated the loosening of one fundus or crural suture. Because of the low prevalence and severity of postoperative recurring symptoms and complications in endomanometric LNF, no redo surgery was required during the follow-up period of 3 years. A recent study by Bardini et al. [37] emphasized the importance of intraoperative HRM, with no patients complaining of dysphagia but recurrent HB in 26.6%, recurrent regurgitation in 13.3%, and atypical symptoms in 13.3%. Postoperative recurrence and complications in this study were higher than our results, possibly due to variation in LES pressure assumed intraoperatively (mean LES pressure was 20.2 mmHg). In contrast, in our study, it was 32.5 mmHg, and the median LES pressure in the postoperative period was 13.5 (11.7–15.0) mmHg, while the median LES pressure in our study was 19 mmHg.

According to another previous study, all postoperative recurrence or complications following LNF were treated conservatively with PPI or endoscopic dilatation, resulting in improved postoperative PD without reintervention [38]. Although endoscopic dilations are the most often used treatment for PD, there are no clinical guidelines on endoscopic dilation in post-fundoplication dysphagia. There is no agreement on the type of dilators, the number, the frequency of sessions, or the maximum optimum diameter. In our hospitals, we used pneumatic dilation with a 35 mm balloon, with 1-2 months between sessions. Intraoperative HRM and endoscopes helped to restore normal physiology and LES pressure with less incidence and severity of recurrent postoperative symptoms and PD requiring multiple dilatation or surgery. In LNF alone in our study, five patients showed tight lower esophageal sphincter with high pressure, failed dilatation, and redo surgery was indicated. Surgical

revision should be reserved as a last choice for patients with severe symptom burdens not managed by PPI and/or endoscopic therapy, as well as evidence of structural abnormality [39]. No redo surgery for our endomanometric LNF group, whereas reoperation has been reported in 13 patients for LNF alone (4 for recurrent HB, 4 for recurrent regurgitation, and 5 for persistent score III dysphagia), which is within the normal range to previous studies [40-41]. The reason for good postoperative results in the endomanometric LNF was assumed to be good visualization of normal anatomy at the esophagogastric junction (by Endoscope) and LES pressure (by intraoperative HRM), allowing for a better return of the esophagogastric junction to normal physiology; all of these factors decrease postoperative recurrent symptoms and complications with no reintervention. Excluding patients with esophageal dysmotility preoperatively was another reason for good postoperative results in the endomanometric LNF. We believe that using endomanometric LNF can reduce postoperative recurrence and complications and increase patient satisfaction. Previous research looked at patient satisfaction after LNF and found up to 80% satisfaction with a recurrence rate of 21.6% [42-43]. Three years after the surgical procedure, 93.3% of patients who underwent endomanometric LNF were highly satisfied with their status (compared to 86.7% in the LNF group) and would repeat the procedure or recommend it to a friend considering such treatment. The study's strengths are the availability of a control group and the acceptable follow-up period.

Furthermore, the operations were carried out by experienced surgeons. Our study's weakness was its retrospective nature, which could lead to selection bias; and the exclusion of individuals with esophageal dysmotility. The low incidence of complications and recurrence constitutes a limitation for conducting a reliable regression analysis to predict these outcomes. It may compromise the statistical power and validity of the model, impeding the identification of significant predictors and the generalization of the results to larger populations. We haven’t

calculated the cost of intraoperative HRM compared to the cost of managing recurrent symptoms due to previous anti-reflux surgery failure **.This non-randomized study is the first step of a project that will culminate in designing and developing a randomized controlled trial to compare the two techniques. Furthermore, we aim to perform a future study comparing the functional outcomes of endomanometric LNF with other techniques such as Toupet or Dor fundoplication.**

Conclusion

Patients submitted to endomanometric LNF showed a favorable trend toward better symptoms control, decreased postoperative complications, better satisfaction, and higher PPI discontinuation compared with those who underwent LNF alone. The outcomes of this study add to the growing evidence supporting the efficacy of intraoperative HRM and endoscopy during LNF. HRM and endoscopy combined with Nissen fundoplication is an effective procedure in patients with severe GERD (DeMeester score >100 and large hiatus hernia >5cm).

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Figure 1. Barium meal in Trendlenburg position shows sliding hiatus hernia

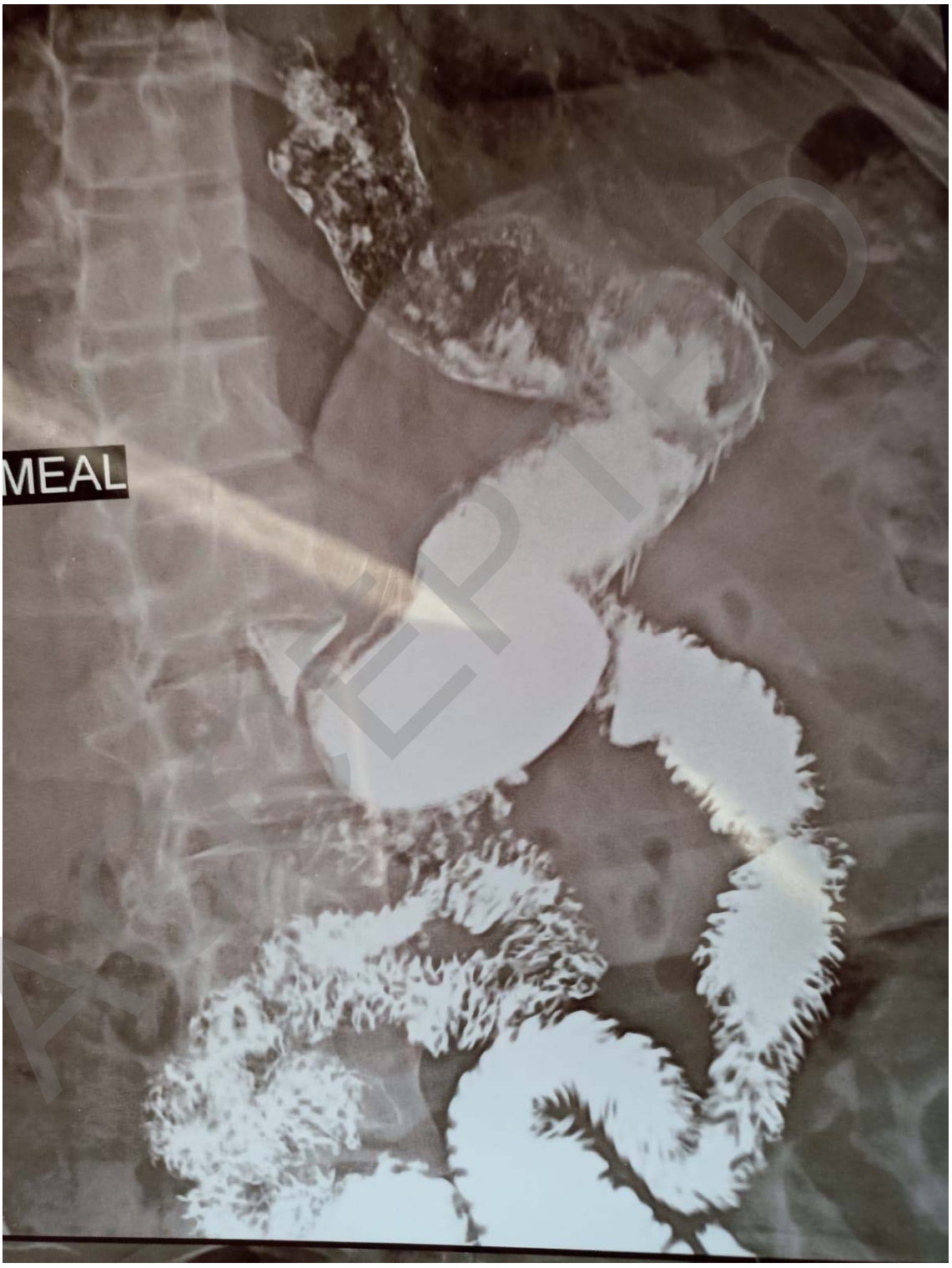

Figure 2. Dissection of the hiatus revealed a large hiatus hernia defect.

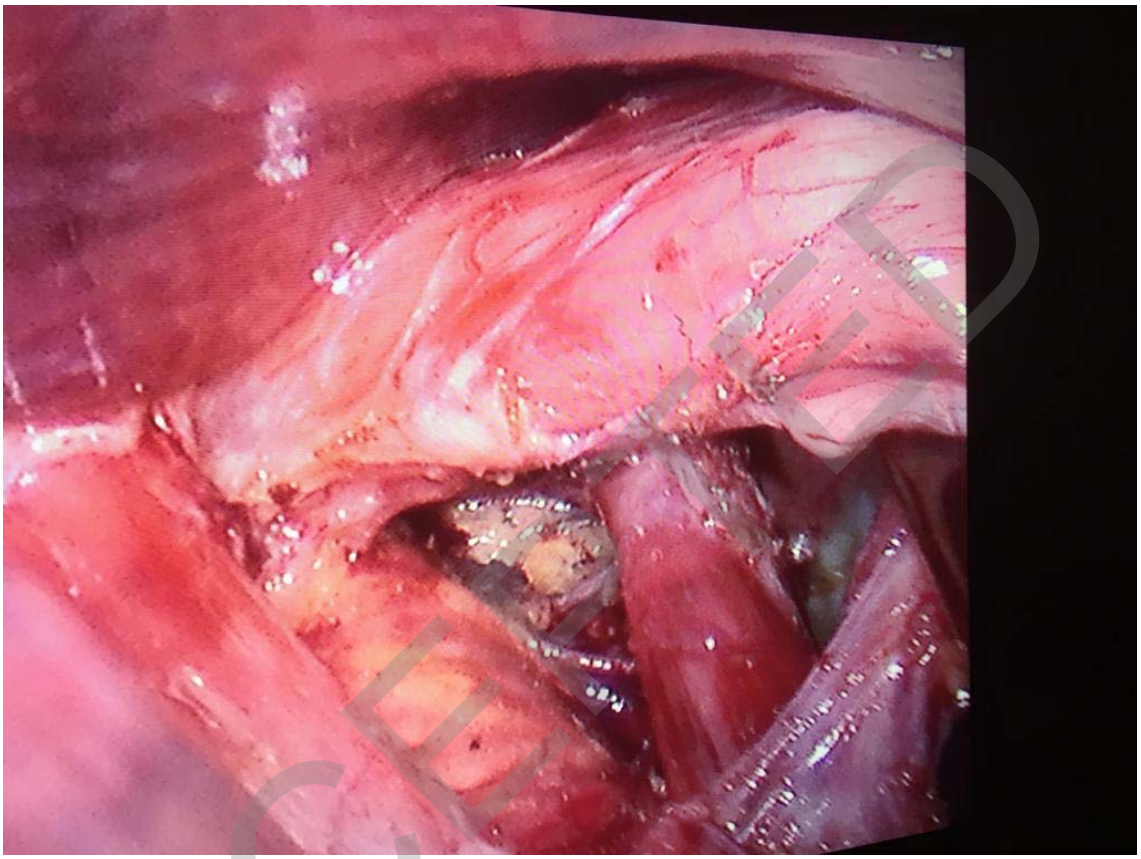

Figure 3. Flow chart of inclusion and exclusion criteria of the studied patients

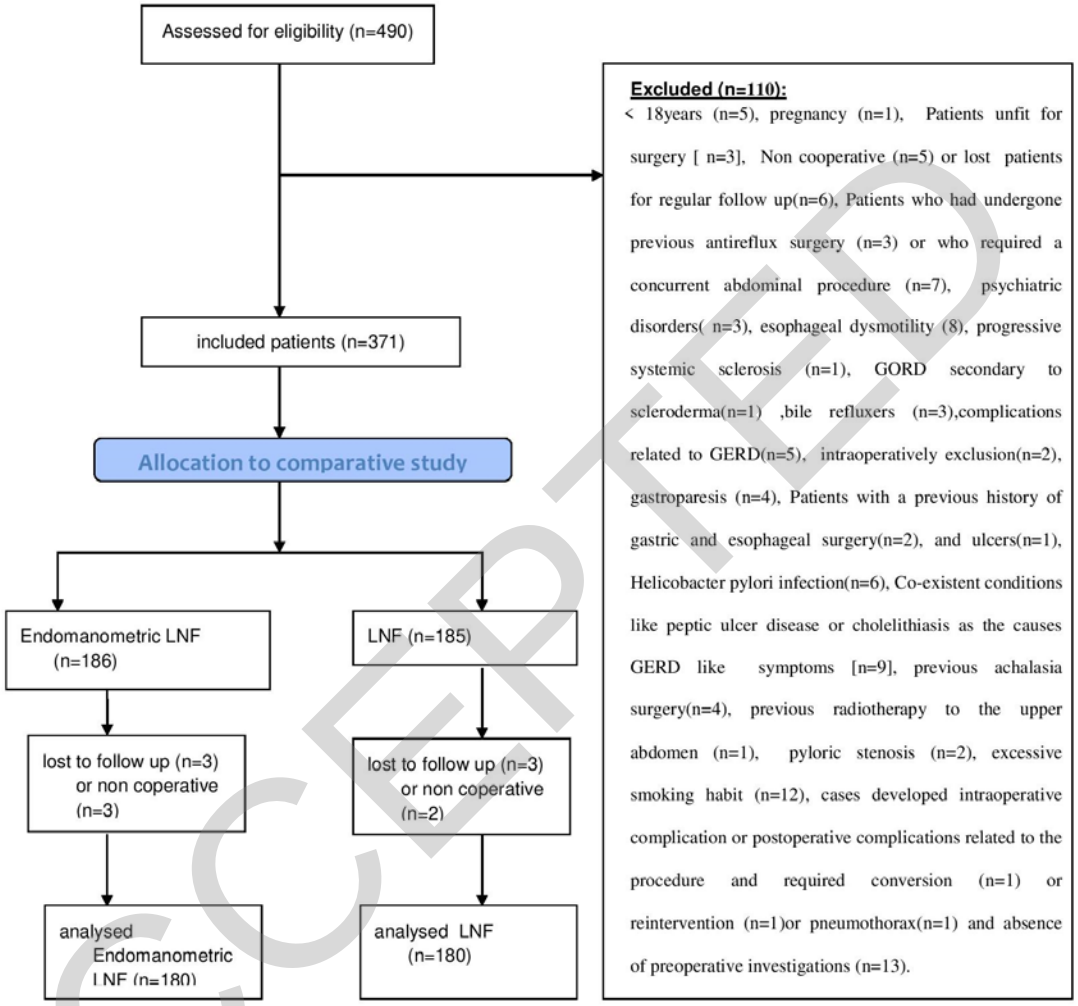

Figure 3

Figure 4. Postoperative outcomes and patient satisfaction of the studied patients.

4A: Appearance of new complications

4B: Postoperative recurrent symptoms

4C: Postoperative dysphagia score

4D: DeMeester score of severity of recurrent symptoms

4E: Patient satisfaction at the end of the study.

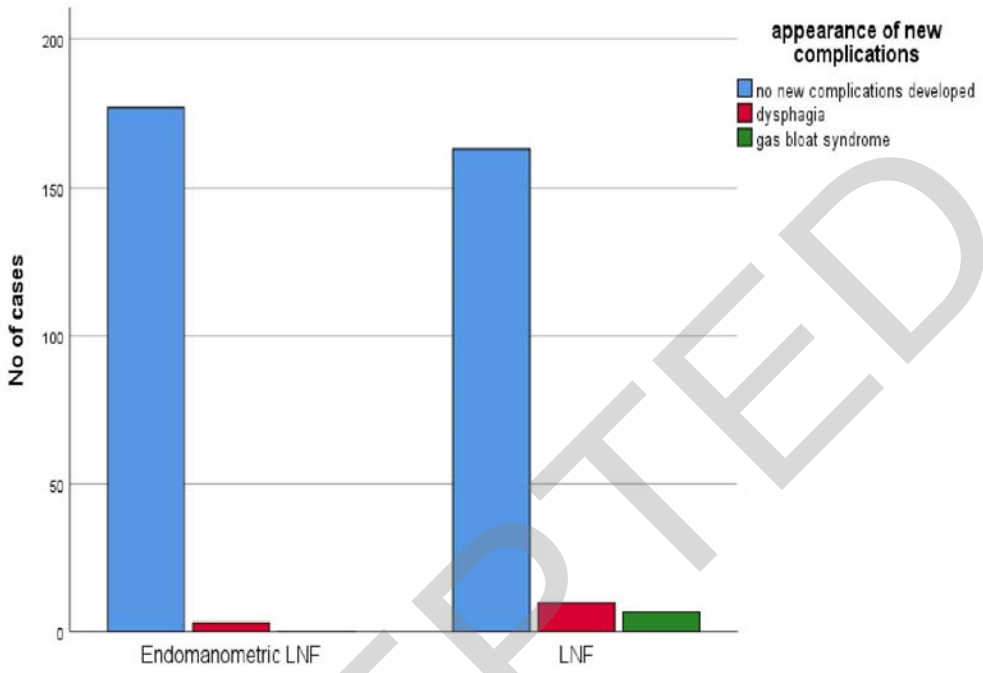

Figure.4 (A)

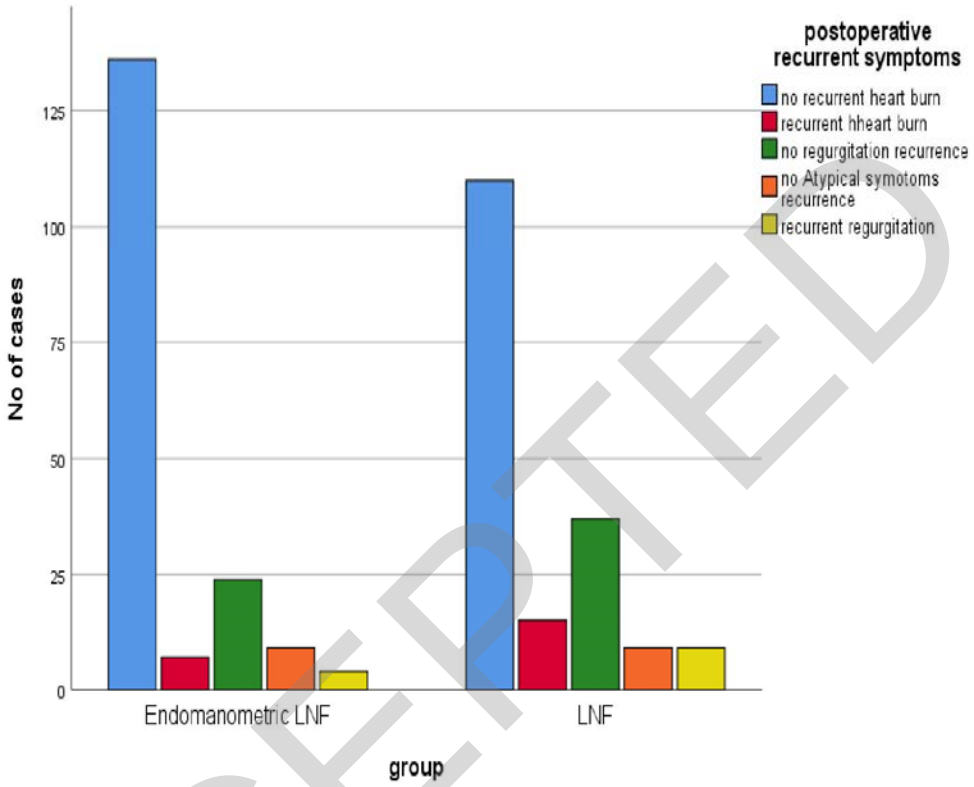

Figure.4 (B)

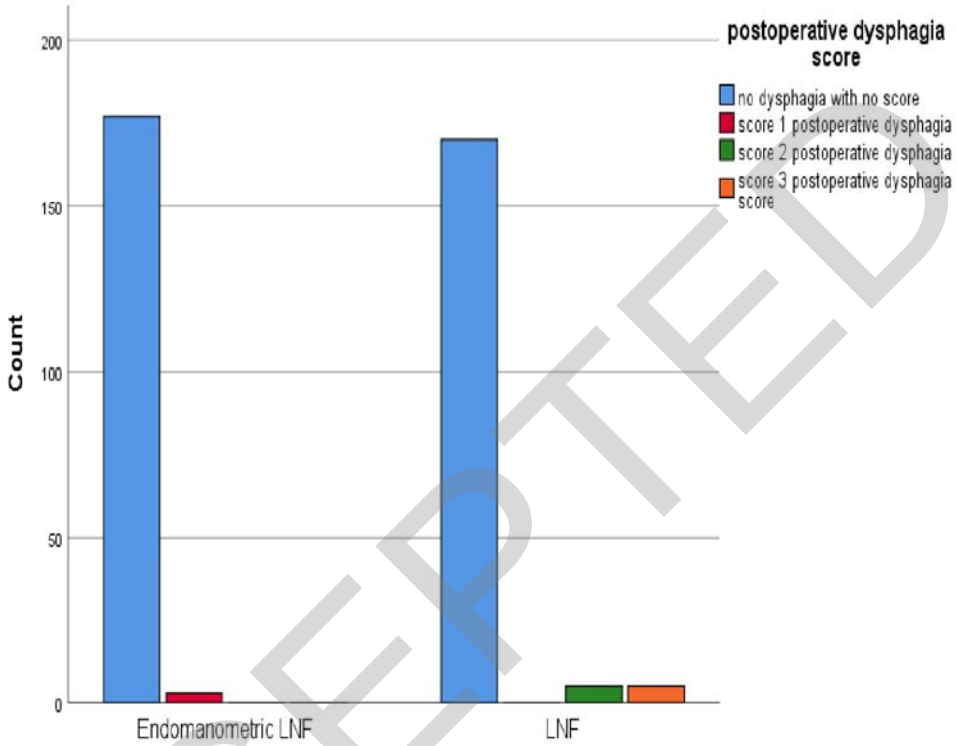

Figure.4 (C)

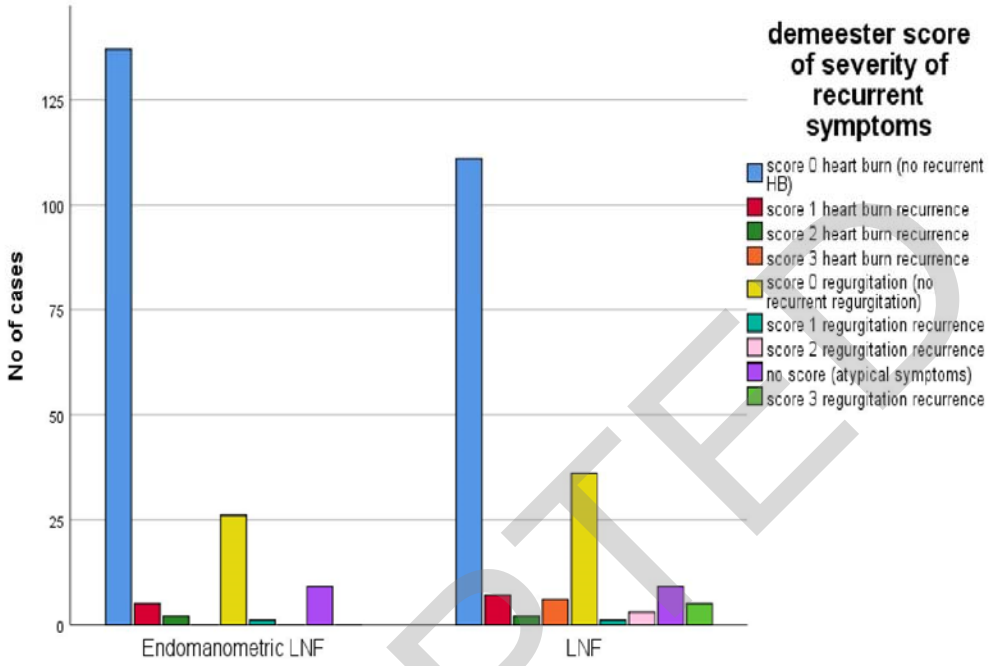

Figure.4 (D)

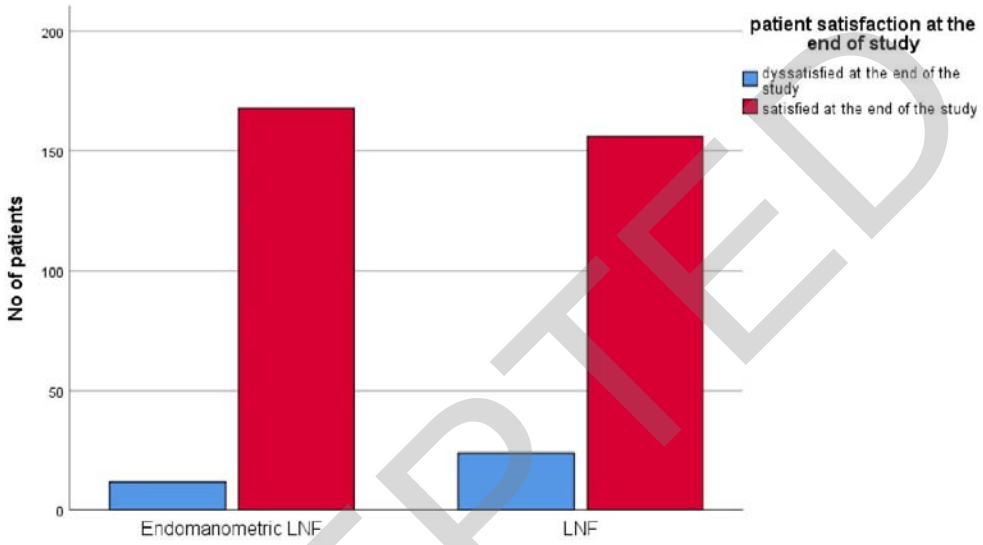

Figure.4 (E)

Table 1. Demographic and baseline characteristics of the studied groups

	Endomanometric LNF (n=180)	**LNF alone (n=180)**	**P value**
Age (years) (mean±SD)	37.98±8.11	38.19±8.15	0.806
Sex		.	.
Male	54(30.0%)	43(23.9%)	0.192
female	126(70.0%).	137 (76.1%)	
Smoker	47(26.1)	39(21.7)	0.324
BMI (mean±SD)	31.38±3.42	31.38±3.42	1.000
Time with symptoms before surgery (months) , median (min-max)	22(10-84)	22(10-83)	0.772
Response to acid-reducing medication preoperatively	. 130(72.2%).	. 136(75.6%).	0.473 .
Hiatus hernia size (cm) (mean±SD)	6.57±0.82	6.54±0.74	0.733
Preoperative esophagitis grading	. 7(3.9%)	. 10(5.6%)	. 0.087
Grade A	8(4.4%)	16(8.9%)	
Grade b	115(63.9%)	113(62.8%)	
Grade C	50 (27.8%)	41(22.8%)	

Grade D			
Preoperative initial symptoms	.		.
Heartburn (HB)	143(79.4%)	125(69.4%)	0.061
Regurgitation	28(15.6%)	46(25.6%)	
Atypical symptoms	9 (5.0%)	9 (5.0%)	
Modified DeMeester score of severity of initial symptoms	.	.	.
No score	9(5.0%)	9(5.0%)	
Score I heartburn	20(11.1%)	18(10.0%)	
Score II heartburn	27(15.0%)	19(10.6%)	
Score III heartburn	96(53.3%)	88(48.9%)	0.634
Score I regurgitation	1(0.6%)	7(3.9%)	
Score II regurgitation	9(5.0%)	11(6.1%)	
Score III regurgitation	18 (10.0%)	28(15.6%)	

Data are presented as mean± standard deviation (SD), median (min-max), or number (percentage); * Significant P-value

Table 2. Intraoperative findings

	Endomanometric LNF	**LNF alone**	**P value**
Operative time	112.36±7.21	59.31±6.05	< 0.001*
Endomanometry-related complications	.	. -.	.
No procedure-related complications	175(97.2%).		
Esophageal wall bleeding	3(1.7%)		
Epistaxis	2(1.1%)		
Time to perform intraoperative manometry	20.29±4.17	-	.
Time to perform intraoperative esophagoscope	21.16±4.33	-	.

Data are presented as mean, standard deviation, or number (percentage); LESP: Lower esophageal sphincter pressure.

Table 3. Oesophageal manometry and DeMeester's pH scoring

	Endomanometric LNF	**LNF alone**	**P value**
Mean lower esophageal sphincter manometry (mmHg)			
Preoperative	6.04±2.19	6.87±2.42	0.001*
Intraoperative	32.58±4.68	----------	
At the end of the study	19.17± 0.38	14.55±1.5	< 0.001*
Preoperative DeMeester's pH scoring			
(median ,min-max)	64(27-81)	63(44-81)	0.099
Total time less than 4	48(34-67)	50(34-67)	0.556
Time pH less than 4 upright	34(22-45)	34(22-45)	0.377
Time pH less than 4 supine	17(9-23)	17(9-23)	0.554
Number of reflux episodes per hour	9(5-18)	10(5-18)	0.296
Number of reflux episodes more than	23(12-34)	23(12-34)	0.961
5 min	119.1	113.13	< 0.001*
Duration of longest episodes in	(101.07-161.77)	(89.11-139.8)	
minutes			
DeMeester's pH score value			

DeMeester's ph score at the end of the study(median, minimum-maximum)	3(1-23)	3(1-6)	0.654
Total time less than 4	3(1-12)	3(1-6)	0.874
Time pH less than 4 upright	3(1-19)	3(1-7)	0.354
Time pH less than 4 supine	3(1-16)	3(1-7)	0.248
Number of reflux episodes per hour	3(1-14)	3(1-7)	0.523
Number of reflux episodes more than 5 minutes	3(3-21)	3(1-7)	0.320
Duration of the longest episode in minutes	11.5 (5.17-47.11)	13.34 (7.54-168.69)	< 0.001*
DeMeester's score value			

Data are presented as mean, standard deviation or median (min-max), * Significant P-value

Table 4. Primary and Secondary outcomes

	Endomanometric LNF	**NF alone**	**P-value**
Patients continue on acid reducing agents at the end of the study	3(1.7%).	13(7.2%)	0.011*
Hiatus hernia (HH) recurrence after surgery	3(1.7%).	10(5.6%).	0.048*
Postoperative esophagitis grading			.
Esophagitis grade A	0(0.00%)	10(5.6%).	0.001*
No esophagitis	180(100%)	170(94.4%)	
Postoperative recurrent symptoms	136(75.6%)	. 110(61.1%)	. 0.012*
No recurrent heartburn	7(3.9%)	15(8.3%)	
Recurrent heartburn	24(13.3%)	37(20.6%)	
No regurgitation recurrence	9(5.0%)	9(5.0%)	
No Atypical symptoms recurrence	4(2.2%)	9(5.0%).	
Recurrent regurgitation			
Appearance of new complications	.		.
No new complications developed	177(98.3%)	163(90.6%)	0.001*
Persistent dysphagia	3(1.7%)	10(5.6%)	
Gas bloat syndrome	0(0 %).	7(3.9%)	

Treatment of recurrent		.	
symptoms or new complications			.
No recurrence or appearance of	163(90.6%)	139(77.2%)	< 0.001*
complications, so No treatment			
Conservative treatment	7(3.9%)	12(6.7%)	
PPI	7(3.9%)	11(6.1%)	
Endoscopic dilatation-one session	3(1.7%).	0(0%)	
Endoscopic dilatation two sessions	0(0%)	2(1.1%)	
Endoscopic dilatation three	0(0%)	1(0.6%)	
sessions	0(0%)	2(1.1%)	
Endoscopic dilatation four sessions	0(0%).	13(7.2%)	
Redo surgery			
Indications of redo surgery			
Recurrent HB	0(0%)	4(2.2%)	< 0.001*
Recurrent regurgitation	0(0%)	4(2.2%)	
Permanent dysphagia score 3	0(0%)	5(2.8%)	
DeMeester score of severity of			
recurrent symptoms			.
Score 0 heartburn (no recurrent	136(75.6%)	110(61.1%)	0.005*
HB)	5(2.8%)	7(3.9%)	
Score I heartburn recurrence	2(1.1%)	2(1.1%)	
Score II heartburn recurrence	0(0%)	6(3.3%)	
Score III heartburn recurrence			
	24(13.3%)	37(20.5%)	
Score 0 regurgitation			

(no recurrent regurgitation)	4(2.2%)	1(0.6%)	
Score I regurgitation recurrence	0(0%)	3(1.7%)	
Score II regurgitation recurrence	0(0%)	5(2.8%)	
Score III regurgitation recurrence	9(5.0%)	9(5.0%)	
No score (atypical symptoms)			
Postoperative dysphagia score	.		.
No dysphagia with no score	177(98.3%)	170(94.4%)	0.007*
Score I postoperative dysphagia	3 (1.7%)	0(0%)	
Score II postoperative dysphagia	0(0%)	5(2.8%)	
Score III postoperative dysphagia	0(0%)	5(2.8%).	
score			
GERD recurrence and severity at	.		.
the end of the study			0.001*
No GERD recurrence at the end of	169(93.9%)	156(86.7%)	
the study	11.(6.1%)	8(4.4%)	
Recurrent mild GERD at the end of	0(0%)	16.(8.9%)	
the study			
Recurrent severe GERD at the end			
of the study			
Patient Satisfaction	.		.
Dys-satisfied at the end of the study	12(6.7%)	24(13.3%)	0.05*
Satisfied at the end of the study	168 (93.3%)	156(86.7%)	

Data are presented as number (percentage); * Significant P-value; HB: Heartburn; GERD: Gastroesophageal reflux disease.