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**Title:**
**Clinical and functional factors influencing the outcome of laparoscopic Nissen fundoplication**

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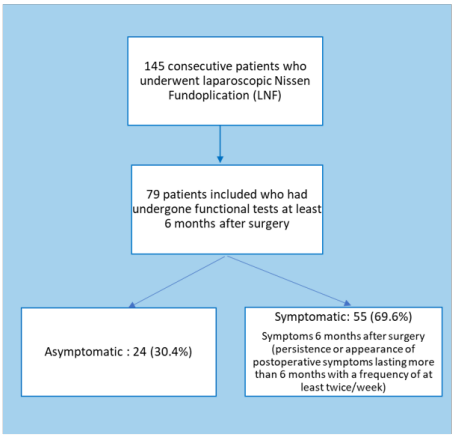
# CLINICAL AND FUNCTIONAL FACTORS INFLUENCING THE OUTCOME OF LAPAROSCOPIC NISSEN FUNDOPLICATION

## Study population




RANDOMIZATION

## Methods

Retrospective, analytical, observational case-control study

**Study variables**

- Postoperative symptoms and type: dysphagia, typical GERD symptoms (heartburn/regurgitation), and others (retrosternal pain/extraesophageal/weight loss).
- Epidemiological-clinical: age, gender, body mass index, and preoperative dysphagia
- HRM: EGJ-morphology, LES resting pressure (mmHg), median IRP-4s (mmHg), distal contractile integral (DCI; mmHg.s.cm), distal latency (seconds), EMD: according to CC v.3.0 and 4.0.
- pH monitoring: AET (%, total, upright, and supine), DeMeester score, gastric AET (%). pH-study result: normal, pathological GERD, and cardia hypercontinence.
- Esophagogram: esophageal emptying (complete/incomplete) and hiatal hernia (yes/no).

**-Statistical analysis**

Chi-square, Mann-Whitney, and Kruskal-Wallis test.
Binary logistic regression models. P values < 0.05

## Outcomes

- Functional and imaging tests are essential in evaluating patients with postoperative symptoms.
- Asymptomatic patients mostly have normal functional tests after LNF, although IRP-4s (95th-percentile) is 20.4 mmHg, higher than proposed in the CC.
- Female gender (OR 4, 95%CI; 1.1-14), preoperative dysphagia (OR 8.2, 95%CI: 1.4-47.6), and IRP-4s (OR 1.2, 95%CI: 1-1.3) are independent factors for postoperative dysphagia.
- Type-III esophagogastric junction morphology on high-resolution manometry (OR 6.1, 95%CI: 2.1-18.1) is independently associated with GERD symptoms
- Hiatal hernia in the esophagogram was associated with reintervention (OR 5.5, 95%CI: 1.6-19.1).

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# Clinical and functional factors influencing the outcome of laparoscopic Nissen fundoplication

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Keywords: Laparoscopic Nissen fundoplication. High-resolution manometry. Dysphagia, GERD symptoms.

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**Abbreviations list**.

LNF: Laparoscopic Nissen fundoplication

GERD: gastroesophageal reflux disease

EGJ: esophagogastric junction

PPIs: proton pump inhibitors PPIs

LES: lower esophageal sphincter

HRM: High resolution manometry

BMI: body mass index

IRP-4s: integrated relaxation pressure over 4 seconds

EMDs: esophageal motility disorders

CC: Chicago Classification

REDO: reoperation

CD: crural diaphragm

IEM: ineffective esophageal motility

EGJOO: esophagogastric junction outflow obstruction

AET: acid exposure time

SD: standard deviation

IQR: interquartile range

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**ABSTRACT**

**Background and aim**. Laparoscopic Nissen fundoplication (LNF) is the gold standard of antireflux surgery. Up to 30% of patients experience symptoms after surgery, with insufficient information available. The main objective is to evaluate epidemiological, clinical, and functional factors associated with symptoms after LNP.

**Methods**: a retrospective case-control study including 79 operated patients (2015-2024). We assessed the relationship between epidemiological data, functional tests, and imaging study results with the occurrence of symptoms after LNF.

**Results**: 24 asymptomatic and 55 symptomatic patients were included. Functional and imaging tests were normal in the majority of asymptomatic patients. IRP-4s (95th percentile) in asymptomatic patients is 20.4 mmHg. Female gender (OR 4, 95%CI; 1.1-14), preoperative dysphagia (OR 8.2, 95%CI: 1.4-47.6), and IRP-4s (OR 1.2, 95%CI: 1-1.3) are independent factors for postoperative dysphagia. Type-III esophagogastric junction morphology on high-resolution manometry (OR 6.1, 95%CI: 2.1-18.1) is independently associated with GERD symptoms. AET showed a trend toward being an independent factor but did not reach statistical significance (OR 1.1, 95%CI:1-1.3). Hiatal hernia in the esophagogram was associated with reintervention (OR 5.5, 95%CI: 1.6-19.1).

**Conclusions**: Asymptomatic patients mostly have normal functional tests after LNF, although IRP-4s normal value (95th percentile) is higher than proposed in the Chicago Classification. Preoperative dysphagia and female gender are independent factors for postoperative dysphagia, which should be considered in the preoperative assessment. Functional and imaging tests are essential in evaluating patients with postoperative symptoms. Dysphagia is associated with higher IRP while GERD symptoms are related to type-III-EGJ on HRM. Similarly, a hiatal hernia on the esophagogram is associated with reintervention.

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## INTRODUCTION

Gastroesophageal reflux disease (GERD) results from the reflux of gastric contents, causing troublesome symptoms and/or complications(1). its prevalence worldwide is 13%(2) and its complex pathophysiology includes dysfunction of the esophagogastric junction (EGJ) and esophageal peristalsis disorders(3).

Medical treatment focuses on acid suppression, with proton pump inhibitors (PPIs) being the drugs of choice(4). Therefore, if there is a poor response to medical treatment, laparoscopic Nissen fundoplication (LNF) is currently considered the treatment of choice. Although its long-term efficacy is over 90%, new, persistent, or recurrent symptoms can occur in up to 30% of cases after surgery (5,6).

Significant postoperative dysphagia occurs in up to 20% of patients and recurrent reflux symptoms like heartburn in approximately 10% (6, 7). Patients with symptoms after LNF require thorough evaluation with functional tests, endoscopy, and radiological studies, as they may have associated structural and functional abnormalities, potentially requiring further interventions. Various parameters of high-resolution esophageal manometry (HRM) have been identified that can help to understand the symptoms experienced by the patients after LNF(8, 9). Despite this, there is a limited number of studies evaluating differences in functional tests between patients with and without symptoms after LNF. Symptomatic patients are expected to exhibit more abnormalities in functional tests concerning EGJ morphology, resting pressure, relaxation, and esophageal motility disorders (EMDs). These abnormalities likely differ depending on the predominant symptom. This study aims to determine the clinical and functional factors influencing the occurrence of symptoms after LNF compared to a control group of asymptomatic patients.

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## METHODS

A retrospective, analytical, observational case-control study approved by the Hospital's Ethics Committee.

**Patients**. We identified 145 consecutive patients who underwent LNF (January 2015-March 2024), including 79 patients who had undergone functional tests at least 6 months after surgery to avoid bias from possible transient dysphagia. Endoscopic and esophagogram data were also analyzed if available.

Inclusion criteria included patients aged ≥ 18 years treated with LNF, with all clinical, HRM, and pH-monitoring data available in the database after surgery. For symptomatic patients, persistence or appearance of postoperative symptoms lasting more than 6 months with a frequency of at least twice/week, and signing informed consent. Exclusion criteria included techniques other than LNF, lack of functional test data, and not having discontinued PPIs seven days prior to the pH-monitoring.

### High-resolution-esophageal-manometry

HRM was performed using a solid-state catheter with 36 circumferential sensors spaced 1 cm apart and an outer diameter of 4.2 mm (Medtronic®). Studies were conducted under basal conditions and supine in all cases and, from 2021 in both supine and sitting positions(10, 11). Only supine results available for all patients were analyzed. The HRM study protocol was carried out in a standardized way(10,11).

### Ambulatory 24-hour pH monitoring

Esophagogastric pH-monitoring without PPIs was performed using a catheter with two sensors 15 cm apart, placed 5 cm above the upper border of the LES and in the stomach, and connected to an external recorder (Medtronic®). Studies were conducted while maintaining routine daily activity, meal schedules, and sleep patterns.

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**Interpretation of HRM and pH monitoring**

HRM data were analyzed using Mano ViewTM version 3.3 software (Medtronic®). EGJ was classified as type-I (crural diaphragm (CD) overlapped with the LES), type-II (sliding: CD and LES separation < 2 cm), and type-III (hiatal hernia: CD and LES separation ≥2 cm). LES resting expiratory pressure was measured without swallowing (normal values: 10-32 mmHg). Median integrated relaxation pressure (IRP-4s) was automatically calculated (normal < 15 mmHg) (10, 11). EMDs were classified according to the Chicago classification (CC)(10,11): normal, achalasia, EGJ-outflow-obstruction (EGJOO), ineffective esophageal motility (IEM), absent peristalsis, hypercontractile esophagus, and esophageal spasm. As these patients were treated with LNF, the CC was used as a guideline to denote the type of EMD.

pH-monitoring data included: total, upright, and supine acid exposure time (AET) and DeMeester score(12). Gastric-AET ≥90% was considered normal. Analysis used normal reference values published by DeMeester(12). Cardia hypercontinence was defined as AET ≤ 0.7% in the total 24-hour period(13).

**Radiological and endoscopic studies**

Most patients underwent a conventional esophagogram and upper endoscopy, with the results evaluated by radiologists or endoscopists. Normal or altered esophageal emptying and hiatal hernia were confirmed based on the radiologist's criteria. Normal or failed fundoplication and hiatal hernia in the endoscopy were assessed according to the endoscopist's criteria.

**Study-variables**

Postoperative symptoms and type: dysphagia, typical GERD-symptoms (heartburn/regurgitation), and others (retrosternal pain/extraesophageal/weight loss).

Epidemiological-clinical variables: age, gender, body mass index (BMI), and preoperative dysphagia

HRM variables: EGJ-morphology, LES resting pressure (mmHg), median IRP-4s (mmHg), distal contractile integral (DCI; mmHg.s.cm), distal latency (seconds), EMD: according to CC v.3.0 and 4.0(12, 13).

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pH-monitoring: AET (%, total, upright and supine), DeMeester score, gastric AET (%). pH-study result: normal, pathological GERD, and cardia hypercontinence.

Esophagogram: esophageal emptying (complete/incomplete) and hiatal hernia (yes/no).

Upper-endoscopy variables: normal LNF, failed LNF, and hiatal hernia.

**Statistical analysis**

In the descriptive analysis, qualitative variables are presented with frequency distribution. Quantitative variables with normal distribution are summarized with mean and standard deviation (SD), and those with asymmetric distribution with median and interquartile range (IQR).

Chi-square was used to compare qualitative variables between groups. Mann-Whitney test was used to compare quantitative variables not normally distributed. When comparing four groups simultaneously the Kruskal-Wallis test was used.

Binary logistic regression models evaluated potential factors associated with postoperative dysphagia or GERD-symptoms after surgery.

A significance level of 5% was used for all tests. IBM SPSS Statistics software (version 26.0) was used.

**RESULTS**

Seventy-nine patients were included, 38 (48.1%) men and 41 (51.9%) women. Of these, 24 (30.4%) were asymptomatic and 55 (69.6%) had symptoms 6 months after surgery. Among the symptomatic, 18 (22.8%) had dysphagia as the main symptom; 17 (21.5%) had typical GERD-symptoms, and 20 (25.3%) had both dysphagia and GERD-symptoms. Symptomatic patients also had other associated symptoms (Figure 1).

**Demographic and clinical characteristics** (table 1)

The mean age was 55.9±14.3 years. Patients with dysphagia were older than asymptomatic (62.6±13.0 vs. 50.5±11.5;p=0.038). Symptomatic patients, especially those with dysphagia, were predominantly women(p=0.009).

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Seventeen (21.5%) patients had preoperative dysphagia; of these, 15 (88.2%) had postoperative dysphagia (p<0.001). Preoperative dysphagia was associated with the need for REDO (52.9% vs.24.2%;p=0.022) or dilation (35.3% vs.6.5%;p=0.002).

**HRM results**

The median IRP-4s in asymptomatic patients was 10.6 mmHg (95th percentile: 20.4 mmHg). When comparing patients with and without dysphagia, differences were found in the IRP-4s, being higher in patients with dysphagia (12.9 mmHg, IQR:8.5-16.3 vs. 9.2 mmHg, IQR:6.5-13.9;p=0.039; figure-2), without differences in other HRM parameters.

Symptomatic patients had more frequent disruption of the EGJ. Significant differences were found when comparing the EGJ-morphology between groups, with a predominance of EGJ-type-III in patients with GERD-symptoms (p<0.001) (Table 1). The frequency of EMDs was higher in symptomatic compared to asymptomatic patients, though this did not reach statistical significance (79.4% vs.9.6%; p=0.08). The type of EMD according to the groups is detailed in figure-3A.

**pH-study**

Table 1 expresses the parameters of the pH measurement. Most asymptomatic patients had normal results. Among the symptomatic patients, those with GERD symptoms more frequently had pathological reflux. Notably, there is a significant frequency of cardia hypercontinence in all groups (Figure 3B).

**Radiological and endoscopic studies**

Table 1 summarizes radiological and endoscopic findings. Incomplete esophageal emptying was more frequent in symptomatic vs. asymptomatic patients(p=0.012); the dysphagia and GERD-symptoms group showed incomplete clearance most frequently (61.1%). Also, hiatal hernia was more frequent, particularly in those with GERD symptoms (66.7%) compared to asymptomatic(p=0.015).

**Multivariate analysis: factors associated with postoperative-dysphagia and GERD symptoms (table 2)**

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The following variables were analyzed concerning postoperative dysphagia: age, gender, preoperative dysphagia, LES resting pressure, IRP-4s, UGE morphology, DCI, EMD, esophageal emptying, and hiatal hernia on esophagogram. Female gender (OR 4, 95% CI:1.1-14.3), preoperative-dysphagia (OR 8.2, 95% CI:1.4-47.6), and higher IRP-4s (OR 1.2, 95%CI: 1-1.3) were independently associated with postoperative dysphagia.

The following variables were taken into account regarding postoperative GERD symptoms: age, gender, LES resting pressure, IRP-4s, UGE morphology, DCI, EMD, AET (total, upright, and supine), DeMeester score, and pH-monitoring result.

Type-III-EGJ on HRM (OR 6.1, 95%CI:2-18.1) was independently associated with GERD symptoms after LNF. AET showed a trend toward being an independent factor but did not reach statistical significance (OR 1.1, 95%CI:1-1.3).

**Subsequent Intervention**

A total of 24 (30.4%) patients required reintervention; 14 (17.7%) underwent REDO to Toupet and 10 (12.7%) had a new Nissen procedure. Specifically, REDO was performed on 6(33.3%) patients with dysphagia, 7(41.2%) with GERD-symptoms, and 11(55%) with both dysphagia and GERD. Factors related to REDO were pathological reflux in the pH study (p=0.001) and hiatal hernia in the esophagogram (p= 0-003). Disruption of the EGJ on HRM was more frequent in REDO cases but did not reach statistical significance(p=0.08).

The following variables were analyzed about REDO: age, gender, basal pressure, IRP-4s, UGE morphology, DCI, EMD, AET, pH-monitoring results, esophageal emptying, and hiatal hernia on esophagogram. In the multivariate analysis, hiatal hernia on the esophagogram was independently associated with REDO (OR 5.5, 95%CI:1.6-19.1).

Ten (12.7%) patients required pneumatic dilation and these showed higher IRP-4s, without statistical significance (15.9, IQR:12-16.2 vs. 10.4, IQR:6.5-14.8; p=0.063).

## DISCUSSION

There are only a limited number of studies that assess differences in the parameters of functional tests comparing patients with and without symptoms after LNF and limited information on possible clinical or functional factors that might predict the appearance

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of symptoms after surgery or the need for reintervention. Moreover, the proposed normal values in the CC (10,11) are probably not applicable after LNF since the anatomy and function of the EGJ change.

This study confirms the epidemiological, clinical, and functional differences between asymptomatic patients and those presenting symptoms of dysphagia, GERD, or both after LNF. HRM reference values obtained in asymptomatic patients are resting pressure of 13.9 mmHg and IRP-4s of 10.6 mmHg (95th percentile: 20.4 mmHg). These values are lower than those described in one study(9) but similar to another(14). Furthermore, the IRP cut-off-point we might consider normal in patients after LNF, according to our results, is 20.4 mmHg, which is close to that of other authors(15) but lower than others, who obtained a value of 29 mmHg(9). In any case, the accepted upper limit in the CC (IRP < 15 mmHg) does not seem applicable, and therefore, it is necessary to standardize reference values for patients treated with LNF. It is also important to note that in asymptomatic patients, EGJ morphology was normal and most did not have EMDs.

Female gender and preoperative dysphagia are independent factors associated with postoperative dysphagia. A higher frequency of postoperative dysphagia has been reported in women in agreement with other authors who describe the female gender as a risk factor for dilation after surgery(7). Up to 88.2% of patients with dysphagia before surgery experienced postoperative dysphagia, which is consistent with other authors(7). Preoperative dysphagia, besides being an independent factor associated with postoperative dysphagia, is related to a higher frequency of REDO. Therefore, factors such as gender and the presence of dysphagia should be considered in the preoperative assessment as women and patients with preoperative dysphagia are more likely to have poorer outcomes after LNF.

HRM provides relevant information to understand patients' symptoms after LNF, particularly the EGJ morphology. Symptomatic patients more frequently exhibit disruption of the EGJ. Type-III-EGJ on HRM is independently associated with the presence of GERD-symptoms after LNF. No HRM parameters were associated with GERD- symptoms in line with other studies(8).

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EGJ relaxation measured by IRP-4s was higher in patients with dysphagia compared to asymptomatic patients and it was an independent factor associated with postoperative dysphagia, coinciding with other studies(8, 9) but not confirmed by other authors(16). However, this does not mean that there cannot be patients with dysphagia after LNF with IRP within normal limits, just as there are patients with achalasia who have a normal IRP(17).

EMDs are also diagnosed more frequently in symptomatic patients, with IEM being the most common, and a higher frequency of EGJOO in patients with dysphagia with or without GERD symptoms.

Higher AET showed a trend toward being an independent factor associated with postoperative GERD symptoms, unlike another study in which the result of pH-monitoring was not associated with symptoms or HRM findings(8). A significant number of patients had hypercontinence of the cardia in both asymptomatic and symptomatic patients. This suggests that the symptoms perceived by patients are not specific and may be related to other factors, such as incomplete esophageal emptying which is more frequent in symptomatic patients. In this regard, we consider esophagogastric pH-monitoring off PPIs is useful for evaluating patients with symptoms after LNF.

Furthermore, 30.4% of symptomatic patients required a REDO, similar to other series(18), with the highest proportion in patients with dysphagia and GERD symptoms (55%), as patients with only dysphagia were reintervened less frequently (33%), similar to what has been reported(19). This could be explained by the combination of functional and anatomic alterations favoring both conditions in patients with dysphagia and GERD-symptoms, thus requiring reintervention. In this regard, the presence of a hiatal hernia on esophagogram is independently associated with REDO, highlighting the fact that herniation of the fundoplication requires reintervention to improve patients' symptoms. Esophagogram better discriminates anatomical alterations after LNF and underscores the importance of conducting a thorough study in these patients' using techniques that evaluate both anatomical and functional alterations. Though, in patients with dysphagia without hiatal hernia, pneumatic dilation can be chosen as a therapeutic option(20), although recent studies do not

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demonstrate clear utility(14). In our series, 12.7% of patients were treated with dilation which aligns with the estimate that between 6-12% of patients undergoing fundoplication will require dilations to relieve dysphagia(9,21).

Our study has limitations as it is retrospective. The lack of standardization in patient follow-up after LNF means the timing and performance of diagnostic tests are not homogeneous. However, other published studies present the same limitation regarding our research. Other comorbidities that may act as confounding factors in post-surgical symptoms were not considered. Furthermore, only the results of HRM in supine were considered, as CC.4.0 was not in effect before 2021. Conducting studies in the seated position could influence the results obtained. However, most of the available studies performed the manometric analysis in supine. Another limitation concerns preoperative dysphagia, which is a relevant factor in postoperative dysphagia. However, in our research, we did not analyze the causes of preoperative dysphagia to determine whether they are the same as those of postoperative dysphagia or different. This would be a subject for analysis in future studies. Despite these limitations, our results provide relevant information regarding patients with symptoms after LNF. Prospective studies with a well-defined and standardized protocol are necessary to monitor patients following LNF. These studies should include functional esophageal tests with HRM performed in supine and sitting positions, pH-study, gastroscopy, and esophagogram. Furthermore, the functional lumen imaging probe offers a valuable tool for evaluating the success or failure of LNF and enhancing patient outcomes (22). Furthermore, there are no established guidelines for monitoring or assessing the appropriate response time to a specific treatment when evaluating the need for reintervention.

In conclusion, asymptomatic patients mostly have normal functional tests after LNF, although IRP-4s ($95^{th}$-percentile) is 20.4 mmHg, higher than proposed in the CC. Therefore, it is important to standardize normal HRM values in patients treated with LNF. Preoperative dysphagia and female gender are independent factors for postoperative dysphagia, which should be considered in the preoperative assessment. Functional and imaging tests are essential in evaluating patients with postoperative symptoms, as they help to understand the possible causes and the need for

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reoperation. In this regard, dysphagia is associated with higher IRP while GERD symptoms are related to type-III-EGJ on HRM and higher AET in the pH-study. Similarly, a hiatal hernia on the esophagogram is associated with REDO.

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**Key point table**

| |
|---|
| **What is Known**<br>● A subset of patients after LNF report persistent or de novo symptoms and require further assessment<br>● High-resolution manometry is important in the evaluation of patients with symptoms after surgery. IRP-4s (95th percentile) after LNF is higher than the value proposed in the Chicago Classification.<br>● The accepted upper limit defining esophageal outflow obstruction in the CC (IRP >15 mm Hg) is not clinically applicable after fundoplication. |
| **Contribution of the study**<br>● This study provides reference values for high-resolution esophageal manometry after LNF in our setting<br>● Demonstrates that female gender and preoperative dysphagia are factors for postoperative dysphagia which should be considered in the preoperative assessment of the patients<br>● Functional and imaging tests are essential in evaluating patients with postoperative symptoms.<br>● Higher IRP-4 is associated with postoperative dysphagia<br>● The evaluation of EGJ morphology with HRM is relevant, as symptomatic patients after LNF show greater disruption of it.<br>● Type III EGJ on HRM is an independent factor associated with GERD symptoms after LNF<br>● Hiatal hernia on esophagogram is an independent factor for reoperation |

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## FIGURES

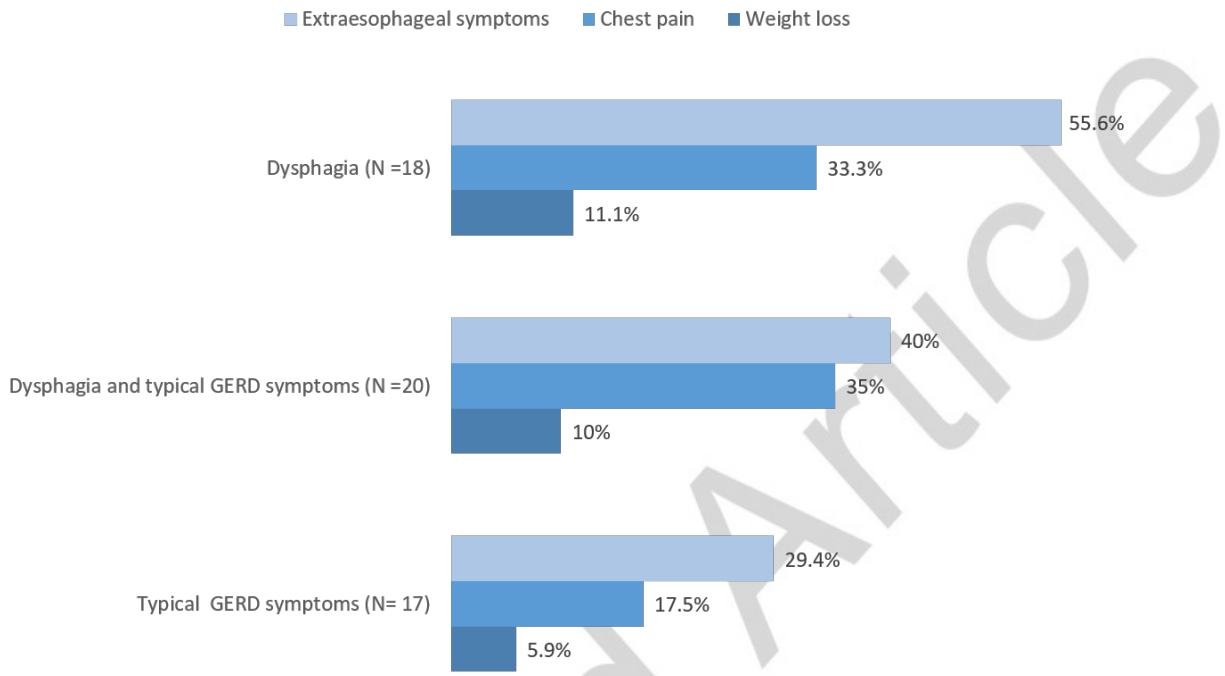


**Figure 1.** Description of symptoms after LNF.

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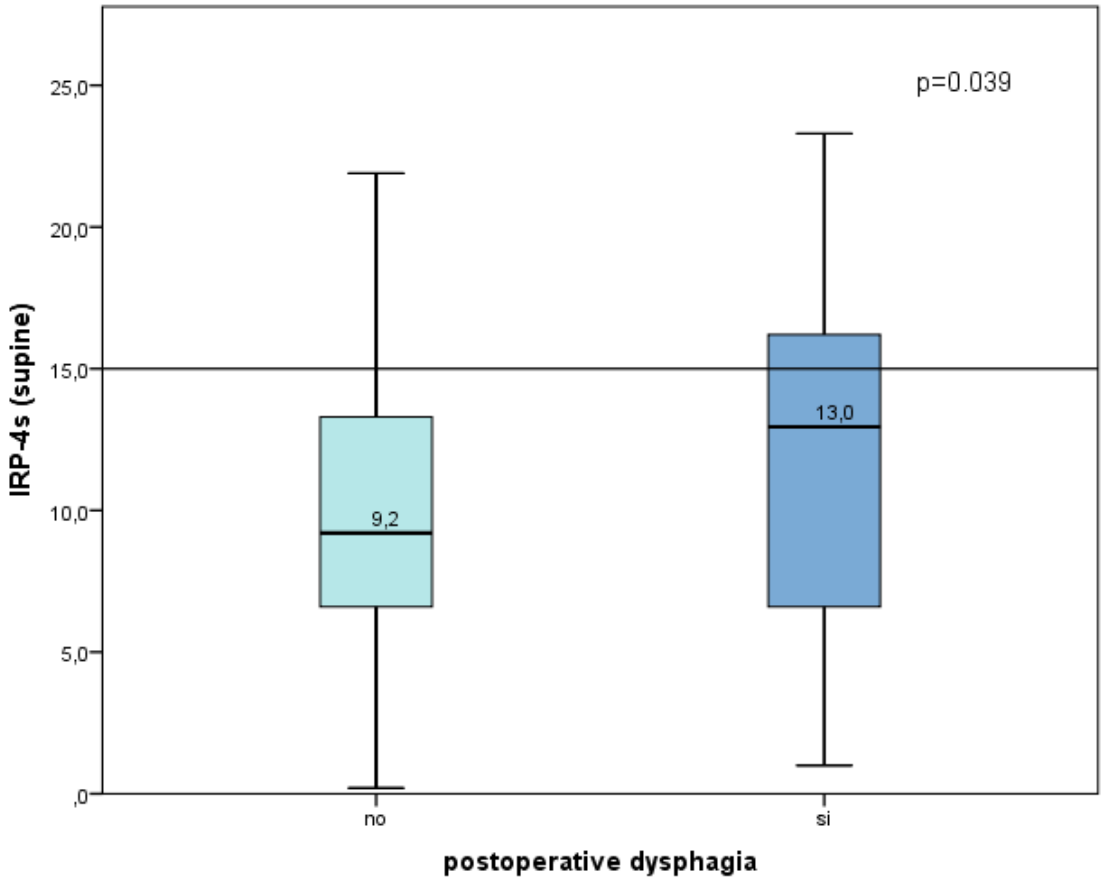


**Figure 2**. IRP-4s and postoperative-dysphagia.

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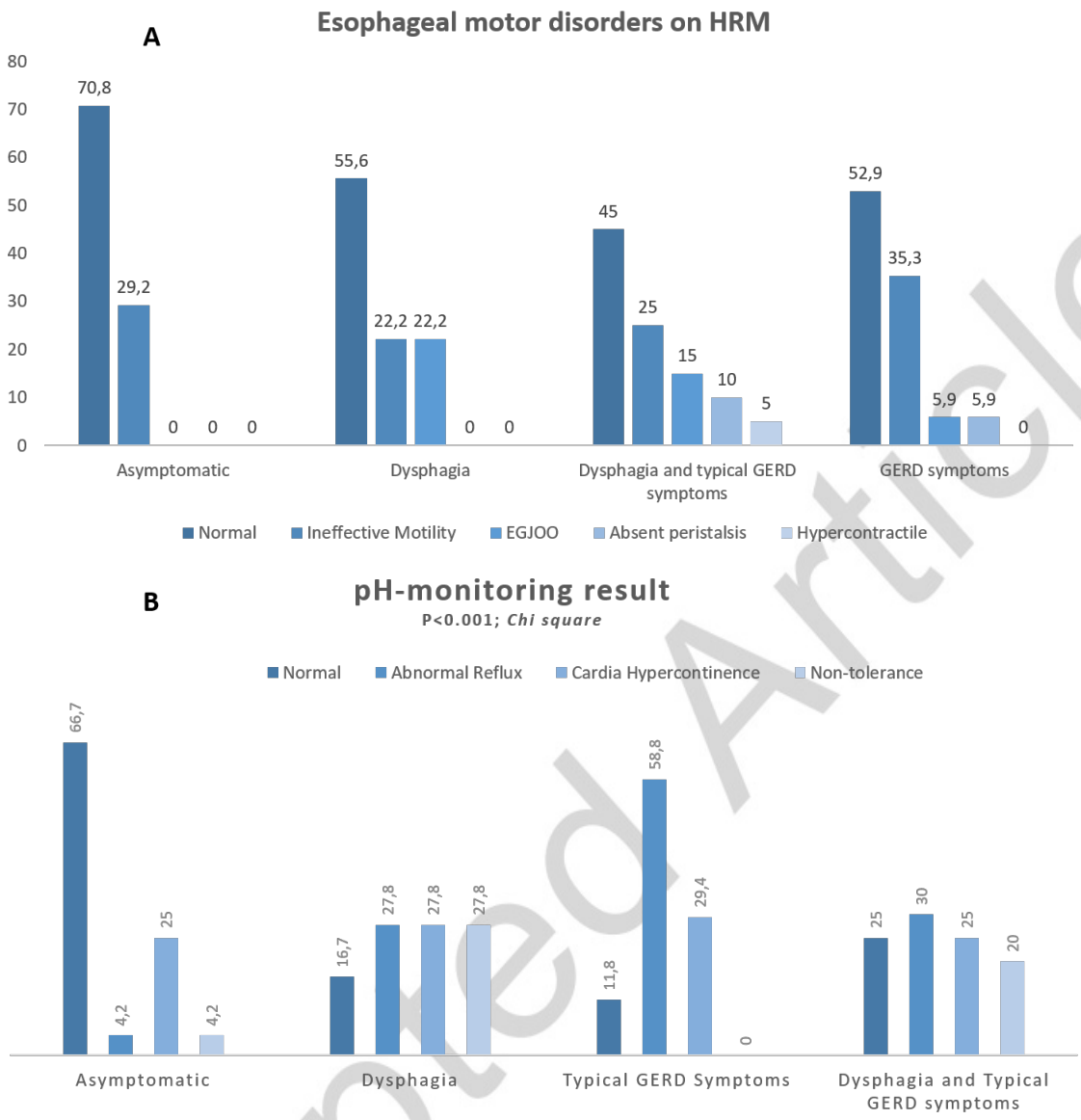


**Figure 3.** EMDs on HRM(A) and pH-monitoring outcome(B) in asymptomatic vs. symptomatic patients

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