

Comparative Study between Nissen Fundoplication and Toupet Fundoplication in Treatment of Hiatus Hernia in Patients with Refractory GERD in Terms of Efficacy and Adverse Outcomes

Ibrahim Hassan Hassan Hassan Rihan^{1*}, Goda Mohammed El- Labban¹,
Haitham Ibrahim Gabr¹, Ahmed Hassan Soliman¹

1-General Surgery Department, Faculty of Medicine, Suez Canal University, Ismaelia, Egypt

*Corresponding Author: Ibrahim Hassan Hassan Hassan Rihan, Email: himaspasepa1@gmail.com, Mobile: +201000369169

ABSTRACT

Background: The degree of anatomical abnormalities and dysfunctions of the barrier preventing stomach contents from refluxing across the esophagogastric junction raises the risk of progressing gastroesophageal reflux disease (GERD).

Aim: This study aimed to compare the long-term effectiveness of laparoscopic Toupet versus Nissen fundoplication for hiatal hernia management and adverse outcomes in Suez Canal University Hospital.

Patients and methods: This prospective comparative research has been performed on General Surgery Department, Suez Canal University Hospital Through the period from January 2022 to January 2024. Cases with GERD who are candidate for operation attending to the General Surgery Department, Suez Canal University Hospitals. The candidates have been divided into two groups (A and B), where group A had laparoscopic Nissen fundoplication and group B underwent laparoscopic Toupet fundoplication.

Results: There was a statistical insignificant variance among examined groups (Toupet vs. Nissen groups) as regards readmission, hernia recurrence, heart burn relief, regurge relief, chest pain relief, chest pain on eating, post prandial fullness, increased flatus, manometry (LES hypotensive), PH DeMeester score, esophagitis grade II and esophagitis grade III. There was a statistically significant variance among examined groups (Toupet and Nissen groups) as regards gas bloating

Conclusion: The study detected an insignificant variance between Toupet and Nissen fundoplication in controlling acid reflux, GERD symptoms, and improving quality of life. However, a significant difference in dysphagia scorings suggests Toupet fundoplication should be recommended before Nissen fundoplication for surgical GERD management.

Keywords: GERD, Laparoscopic Toupet, Nissen fundoplication.

INTRODUCTION

Gastroesophageal reflux disease demands continuous management with medications and alteration in lifestyles. The natural history of gastroesophageal reflux disease has undoubtedly been influenced by pharmacotherapy, particularly the utilization of anti-secretory medication. On the other hand, cases with severe illnesses can benefit from operation to prevent recurrence ^[1].

Gastroesophageal reflux operation is designed to correct functional and anatomical defects in the esophagogastric junction. The decrease of a hiatal hernia, the development of a fundal wrap to improve the LES and its resting pressure, and the proximity of the diaphragmatic crura are all examples of corrective methods ^[2].

Gastroesophageal reflux disease symptoms are frequently related to hiatal hernia, a surgical condition. Although type I sliding hiatal hernias comprise the majority of cases, paraesophageal hernia (PEH) accounts for around between five and ten percent of all hiatal hernia cases and may result in significant mortality and morbidity due to obstruction, hemorrhage, strangulation, and volvulus ^[3].

GERD is a common clinical condition distinguished by the reflux of stomach contents into the oropharynx or esophagus through the lower esophageal sphincter (LES), resulting in pain and/or damage to tissue of the esophageal

significant enough to disrupt a case's quality of life ^[4]. The diagnosis of GERD is dependent on a mix of clinical manifestation, responsiveness to acidity suppression drugs & objective testing utilizing a pH probe (esophageal pH monitor, Barium swallow, esophageal manometry and upper endoscopy) ^[5].

Type III hernias, characterized by the gastroesophageal junction and fundus herniating through the hiatus, are assessed to account for more than ninety percent of all cases with PEH, whereas type IV hernias, which involve structures other than the stomach within the hernia sac, and type II hernias, where the fundus herniates while the gastroesophageal junction remains in its normal anatomical site, are less prevalent. In symptomatic cases, the most prevalent surgical methods for PEH repair are laparoscopic, which may involve mesh reinforcement and/or an anti-reflux procedure ^[6].

In the treatment of cases with GERD & hiatus hernia, the laparoscopic Toupet fundoplication (LTF) has been increasingly considered as a result of the development of minimally invasive surgery. In comparison with the Nissen fundoplication, systematic evaluations and randomized clinical trials have demonstrated comparable outcomes with regard to control of reflux and a reduced incidence of side effects ^[7].

Nevertheless, the LTF's lasting reputation for poor long-term reflux control and reduced durability may be

attributed to the technical differences involving the degree of the wrap (180° versus 270°), the type of gastro-phrenopexy involved and the extent of fundic dissection [8].

A number of randomized controlled trials have been conducted to assess the treatment of GERD by comparing open and laparoscopic Toupet and Nissen fundoplication. The majority of these investigations have shown those who undergo Toupet fundoplication experience reduced rates of dysphagia, while there are no variances in the control of heartburn. Additionally, numerous retrospective investigations that have compared Toupet and Nissen fundoplication have established that those who undergo Toupet fundoplication have inferior prolonged reflux control [9].

The present research aimed to compare the prolonged effectiveness of laparoscopic Toupet against Nissen fundoplication for hiatal hernia management and adverse outcomes in Suez Canal University Hospital.

PATIENTS AND METHODS

This prospective comparative research has been performed in General Surgery Department, Suez Canal University Hospital through the period from January 2022 to January 2024. Cases with GERD who were candidate for operation attending to the General Surgery Department, Suez Canal University Hospitals, and fulfilled the inclusion criteria were enrolled in this research. The candidates were divided into two groups (A and B), where group A had laparoscopic Nissen fundoplication and group B underwent LTF.

Inclusion criteria: Cases who were diagnosed with GERD prior to surgery, insufficient control of symptoms and illness, resistant to medical treatment (Persistent symptoms following twelve weeks of maximal medical treatment, recurrence upon stop of medication and non-compliance with treatments or incapability to tolerate medical treatments), GERD complications, like Barrett's esophagus, esophageal ulcers, intractable esophagitis, hemorrhage & pulmonary complications (recurrent aspiration), and cases with hiatal hernias that were confirmed radiologically or endoscopically despite receiving adequate medical care. Pharmaceutical costs are increasing due to alteration in lifestyle, lifelong medical therapy, and increased dosages.

Exclusion criteria: Cases with achalasia, patients developed GERD post-sleeve gastrectomy, morbidly obese individuals (BMI above thirty-five kilograms per square meter) and patients with HH type II, III, and IV.

$$n = 2 \left[\frac{(Z_{\alpha/2} + Z_{\beta}) * \sigma}{\mu_1 - \mu_2} \right]^2$$

Sample size:

The size of the sample has been calculated according to the following formula:

Where:

- n= sample size= 26 participants in each group
- $Z_{\alpha/2} = 1.96$ (The critical value that separates the central ninety-five percent of the Z distribution from the five percent in the tail)
- $Z_{\beta} = 0.84$ (The critical value that distinguishes the lower twenty percent of the Z distribution from the upper eighty percent)
- $\sigma =$ The estimation of the standard deviation (in Toupet group) = 6.5
- $\mu_1 =$ Mean gastrointestinal quality of life index score after surgery in the Toupet group= 123.4
- $\mu_2 =$ Mean gastrointestinal quality of life index score after surgery in in the Nissen Fundoplication group= 118.2. So, the required sample size was 26 participants in each group **Zügel et al.** [10].

Sampling technique: Convenience sampling method were used where all cases who met the inclusion criteria and were undergoing surgical management for gastroesophageal reflux disease at the Faculty of Medicine, Suez Canal University, throughout the research period have been recruited. Selection of the procedure was based on preoperative manometric studies, barium swallow, upper GIT endoscope, 24-hour PH monitoring and impedance.

Ethical considerations: The data that were collected from participants were confidential. The research participants weren't identified by name in any publication or report that addressed this research. The nature and goal of the research, as well as the risk-benefit evaluation, have been explained to the participants prior to their admission to this study. Informed consent has been obtained from each participant. Approval of Ethics Committees of General Surgery Department, Suez Canal University Hospital was obtained. The Helsinki Declaration was followed throughout the study's conduct.

RESULTS

There was a statistically insignificant variance among examined groups (Toupet and Nissen groups) regarding age, gender, BMI and chronic illness (Table 1).

Table (1): comparing of general characteristics among examined groups

		Toupet (Number = 26)		Nissen (Number = 26)		Stat. test	P-value
Age (years)	Median	33		29		MW = 243	0.082 NS
	IQR	28.75 – 46.25		24.75 – 39.5			
Sex	Male	9	34.6%	6	23.1%	X ² = 0.84	0.358 NS
	Female	17	65.4%	20	76.9%		
BMI (Kg/m ²)	Median	24		23		MW = 336	0.971 NS
	IQR	21 – 26.25		21.75 – 26.25			
Chronic illness	NCI	13	50%	16	61.5%	X ² = 0.82	0.844 NS
	DM	6	23.1%	4	15.4%		
	HTN	5	19.2%	4	15.4%		
	Asthmatic	2	7.7%	2	7.7%		

MW: Mann White U test, X²: Chi-square test, NS: p-value above 0.05 considered non-significant

Table (2) illustrated a statistically insignificant variance (**p-value equal 0.07**) among examined groups (Toupet and Nissen groups) regarding operative time.

Table (2): comparative analysis of operative time among examined groups

		Toupet (Number = 26)		Nissen (Number = 26)		Stat. test	P-value
Operative time (min)	Mean ±SD	89.7 ± 15.6		81.2 ± 16.9		T = 0.17	0.07 NS
	Range	72 - 132		60 – 116			

Table (3) illustrates that there was a statistically insignificant variance among examined groups (Toupet vs. Nissen groups) regarding esophagitis grade, manometry, Hills grade, Gastric ulcer, Defect size and PH DeMeester score.

Table (3): Preoperative characteristics between Toupet and Nissen groups.

		Toupet (Number = 26)		Nissen (Number = 26)		P-value
Esophagitis grade	Grade II	3	11.5%	3	11.5%	.071 NS
	Grade III	9	34.6%	7	27%	
	Grade IV	14	53.9%	16	61.5%	
Manometry	LES normotensive	0	0%	0	0%	1.0 NS
	LES hypotensive	26	100%	26	100%	
Hills grade	Grade III	9	34.6%	6	23.1%	0.09 NS
	Grade IV	17	65.4%	20	76.9%	
Gastric ulcer	No	23	88.5%	21	80.8%	0.89 NS
	Yes	3	11.5%	5	19.2%	
Defect size	3 cm	10	38.5%	10	38.5%	0.888 NS
	4 cm	13	50%	14	53.8%	
	5 cm	3	11.5%	2	7.7%	
PH DeMeester score	Median	17		16		0.977 NS
	IQR	15 - 18		16 – 18		

X²: Chi-square test

There was a statistically insignificant variance among examined groups (Toupet vs. Nissen groups) as regards readmission, hernia recurrence, heart burn relief, regurge relief, chest pain relief, chest pain on eating, post prandial fullness, increased flatus, manometry (LES hypotensive), PH DeMeester score, Esophagitis grade II and Esophagitis grade III. There was a statistically significant variance among examined groups (Toupet and Nissen groups) as regards gas bloating (Table 4).

Table (4): comparative analysis of postoperative outcome among examined groups.

	Toupet (Number = 26)		Nissen (Number = 26)		P-value
Readmission	0	0%	1	3.8%	0.08 NS
Hernia recurrence	2	15.4%	1	3.8%	0.158 NS
Heart burn relief	20	76.9%	21	80.8%	0.82 NS
Regurge relief	22	84.6%	23	88.5%	0.685 NS
Chest pain relief	25	96.2%	22	84.6%	0.158 NS
Dysphagia (Solid food)	1	3.8%	7	26.9%	0.03
Chest pain on eating	1	3.8%	4	15.4%	0.158 NS
Gas bloating	2	4.6%	7	26.9%	0.04
Post prandial fullness	3	11.5%	7	26.9%	0.159 NS
Increased flatus	5	19.2%	7	26.9%	0.51 NS
Manometry (LES hypotensive)	5	19.2%	3	11.5%	0.09 NS
PH DeMeester score (Median, IQR)	15.2 (14.3-15.8)		14.9 (14.5-15.3)		0.37 NS
Esophagitis grade II	7	27%	9	34.6%	.071 NS
Esophagitis grade III	3	11.5%	1	3.8%	

There was a statistically insignificant variance between studied groups (Toupet and Nissen groups) as regards total heartburn score, total regurgitation score and total QOL score (Table 5).

Table (5): comparative analysis of outcome among examined groups

		Toupet (Number = 26)	Nissen (Number = 26)	MW	P-value
Total heartburn score	Median	9.5	9	332	0.761 NS
	IQR	7 - 12	7 - 12		
Total regurgitation score	Median	8.5	9	328.5	0.861 NS
	IQR	7 - 11.25	7 - 11.25		
Total QOL score	Median	16	17	327.5	0.847 NS
	IQR	14.75 - 23	15 - 23.25		

DISCUSSION

Continued dysphagia following operation was a problem with the early classic Nissen procedure and has been identified as a continuous source of morbidity following procedure in laparoscopic antireflux procedures. In reality, the tolerance for postoperative dysphagia have been reduced by the introduction of laparoscopic antireflux surgery. In some cases, dysphagia has been raised from a natural side effect of the procedure to an actual complication due to the inflated expectations of a rapid and simple recovery from a less invasive approach. The Nissen fundoplication method has been developed over time with the specific objective of reducing this complication [11]. Laparoscopic fundoplication is a complicated technique that demands a well-defined learning curve [12].

In order to prepare the retroesophageal window and the crura, dissect wall of the fundus, and construct a symmetric wrap without losing spatial orientation, it is crucial to have a clear field of view. In comparison with the Nissen fundoplication, the technical challenges of the LTF are exacerbated by the requirement for stomach manipulation & suturing on both sides of the esophagus. Despite the fact that experienced surgeons can partially mitigate for the absence of stereoscopic depth perception on a two-dimensional demonstrate, visual cues and laparoscopic proficiency are frequently diminished or lost throughout the procedure, which contributes to the fatigue of the surgeon [13, 14].

Consequently, it may be crucial to reinforce or develop substitute visual cues, particularly for trainee surgeons. Previous research has demonstrated that the impact of incompetence can be mitigated and surgical results may be enhanced through training in laparoscopic anti-reflux operation under the supervision of expert surgeons [15].

Five sizable RCTs comparing LTF and LNF were published from 2007 to 2010 [16-20]. These individual studies have not been the subject of a meta-analysis since they were unable to conclusively demonstrate any differences in results between the two techniques. The included studies' surgical methods were uniform and largely the same. Every patient received a laparoscopic 200–270° partial or 360° total fundoplication. All but one of the trials involved crural repair, regular bougie usage, or fixing the wrap to the oesophagus. Although there has been evidence that routine vs non-routine division of small gastric arteries does not affect the result of fundoplication, the study in question was included in this evaluation despite not routinely dividing these veins.

Postoperative reflux recurrence: The level of reflux control following posterior PF (as determined by twenty-four-hour ambulatory pH monitoring) is somewhat

inferior to that attained by TF, as indicated by data from previous investigations [20, 21]. Conversely, the current investigation demonstrated that there was a statistically insignificant variance (p-value equal 0.685) in the total regurgitation score between the two groups that were examined (Toupet and Nissen). There were 22 patients (84.6%) with regurge relief in Toupet group versus 23 patients (88.5%) in Nissen group.

Excessive variability was seen in the short-term outcomes of surgical reflux recurrence, which were assessed throughout the literature. The random effects model was utilized to aggregate the data, and this parameter remained constant among the two arms (RR = 1.30, P = .65, 95% CI, [.42, 4.05] [7, 14]. The prolonged results of reflux recurrence following operation have not been significantly different among the two arms in additional research (RR = 1.29, ninety-five percent CI, [.86, 1.92], P-value equal .22) [19, 22]. According to Swedish research, the effectiveness of antireflux repair declined when the laparoscopic approach was introduced. Patients also complained of significant mechanical side effects from the procedure, which led to a high failure rate due to recurrent reflux.

Postoperative heartburn: During the current study there was a statistically insignificant variance (p-value equal 0.85) among examined groups (Toupet and Nissen groups) regarding total heartburn score. There were 20 vs. 21 patients with heartburn relief in both groups, respectively. The short-term results of heartburn following surgery have been evaluated in three investigations. The meta-analysis of the heartburn following operation showed an insignificant variance between the two arms (RR = 1.24, ninety-five percent CI, [.73, 2.10], P-value equal .42). In four investigations, the prolonged results of postoperative heartburn were evaluated, and an insignificant variance was observed among the two arms (RR = .75, ninety-five percent CI, [.44, 1.27], P -value equal .28) [16-18].

Postoperative dysphagia: Dysphagia persists as a concern subsequent to antireflux operations. The overcorrection of the basal tone of the LES, which is induced by wrapping the top of the fundus around the EGJ, may be a significant mechanism behind this [17]. Another contributing mechanism to the initial symptom's indicative of compromised transfer of bolus is the presence of early alterations following surgery (e.g., scarring and edema), the majority of which are reversible. An essential finding from this and other researches is that clinically significant chronic dysphagia does not appear to be a significant clinical problem following any type of antireflux operation performed in an expert center [19-21].

Conversely, the outcomes of the current investigation indicated that there was a statistically significant variance (p-value equal 0.03) in dysphagia to solid food among the groups that were examined (Toupet and Nissen). There were 1 patient (3.8%) with dysphagia in Toupet group versus 7 patients (26.9%) in Nissen group. The short-term results of dysphagia following operation were evaluated in five investigations [16-20]. This parameter did not vary among the two arms (RR = 1.60, ninety-five percent CI, [.68, 3.74], Chi2, P-value equal .65; I2 = 86%). We believe that the short monitoring period of the research conducted by **Higgins** [19], which was immediate, could have influenced the heterogeneity by investigating the potential causes of heterogeneity. The heterogeneity significantly decreased and the outcome favored LTF following excluding this research (RR = 2.26, ninety-five percent CI, [1.56, 3.27], P -value less than .0001). The prolonged results of dysphagia following surgery were evaluated in six investigations, which demonstrated a preference for LTF (RR = 2.28, ninety-five percent CI, [1.43, 3.63], P-value equal .0005).

Postoperative relieve of chest pain: Our findings showed that there was a statistically insignificant variance (p-value equal 0.158) among examined groups (Toupet and Nissen groups) regarding chest pain relief. There were 25 patients (96.2%) with chest pain relief in Toupet group versus 22 patients (84.6%) in Nissen group. The short-term results of chest pain following operation were evaluated in prior research, and insignificant variance was observed among the two arms (RR = 1.18, ninety-five percent CI, [.68, 2.06], P-value equal .55). Additionally, the long-term of the chest pain following operation demonstrated extreme heterogeneity. Consequently, the random effects model has been utilized to aggregate data. This parameter did not vary among the two arms (RR = 1.30, ninety-five percent CI, [.10, 16.51], P-value equal .84) [16, 19, 23].

Postoperative DeMeester scores: The prolonged results of **DeMeester** scores were evaluated in four investigations [17-20]. The meta-analysis of the **DeMeester** scores following operation demonstrated excessive heterogeneity. Consequently, the random effects model has been utilized for collecting data. The meta-analysis of the **DeMeester** scores didn't demonstrate a significant variance in this result among the two arms (MD = 0.26, ninety-five percent CI, [-2.59, 2.06]; P-value equal .82; Chi2, P -value equal .18; I2 = 39%).

Furthermore, the current investigation demonstrated that there was a statistically insignificant variance (p-value equal 0.37) in the PH **DeMeester** score among the groups that were examined (Toupet vs. Nissen). In the Toupet group, the median score (IQR) was 15.2 (14.3-15.8). The

median score (IQR) in the Nissen group was 14.9 (14.5-15.3).

CONCLUSION

In regards to control acid reflux, GERD symptom control, and quality of life enhancement, this research did not show any distinction between Toupet fundoplication and Nissen fundoplication. Nevertheless, the outcome of a statistically significant variance in dysphagia scores in favor of Toupet fundoplication indicating Toupet fundoplication should be recommended as an alternative to the more frequently conducted Nissen fundoplication for surgical management of GERD.

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