

EVALUATION OF THE TAILORING CONCEPT OF OESOPHAGEAL ANTIREFLUX SURGERY

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Background: A variety of antireflux operations exists for patients with gastroesophageal reflux disease. However, controversy exists with regard to the choice of operation between complete 360o Nissen Fundoplication versus partial 270o Toupet fundoplication. Most surgeons operate using the concept of "tailored approach", which depends on the degree of preexisting oesophageal motility. Some recent studies abandoned this approach since "tailoring" the operation does not prevent dysphagia occurrence. In view of the still controversial opinion regarding the tailoring concept of antireflux procedure, this prospective, randomized study was done to evaluate the two operative techniques with the objective to determine the impact of preoperative normal and abnormal oesophageal motility on the outcome.

Methods: The present study was conducted on eighteen patients with chronic symptomatic GORD. The preoperative assessment included clinical evaluation, radiological study, upper gastro- intestinal endoscopy with biopsy, and oesophageal manometry with ambulatory PH monitoring. Surgery (9 Nissen and 9 Toupet fundoplication) was performed laparoscopically in fourteen patients and by the conventional open technique in the rest. Surgeries were done in a randomized fashion regardless of the motility status. The perioperative data and complications were compared between the two surgical groups. Follow up was done at one, three and six months using the same preoperative clinical, radiological, endoscopic and manometry studies and the results were compared between the two motility groups.

Results: Oesophageal dysmotility did not affect the outcome after either Nissen or Toupet fundoplication in that improvement and relief of heartburn and regurgitation as well as reflux control on 24-hour pH monitoring and healing of oesophagitis were similar in patients with both normal and abnormal oesophageal motility.

Conclusion : Tailoring antireflux surgery to oesophageal motility is not indicated, since motility disorders are not correlated with postoperative dysphagia.

Key words: Gastro-oesophageal reflux disease (GORD), Antireflux surgery, Nissen fundoplication, Toupet fundoplication.

INTRODUCTION

Gastro-oesophageal reflux disease (GORD) is the commonest upper digestive disorder with approximately 45% of the population having reflux symptoms. It affects a large group of patients and has a negative impact on quality of life. In addition, this disorder is associated with considerable long term morbidity and mortality. Symptoms of GORD include retrosternal burning and regurgitation, which are highly predictive of acid exposure to the oesophageal mucosa^(1,2). It is accepted that in GORD, a functional defect of the lower oesophageal sphincter (LOS) is of major etiologic importance. However, the role of motor abnormalities of the oesophageal body in the pathogenesis, clinical symptoms and outcome of GORD is

poorly understood^(3,4).

A variety of antireflux operations exists for patients with GORD. However, controversy exists with regard to the choice of operation between complete 360o Nissen fundoplication versus partial 270o Toupet fundoplication. Nissen fundoplication is used very frequently but it has a relatively high incidence of wrap related complications such as bloating, inability to blech and dysphagia. Partial wrapping has been reported to be equally effective but associated with fewer unfavourable post operative symptoms⁽⁴⁻⁶⁾. In addition there is some controversy with regard to the proper choice of operation in patients with poor oesophageal motility. Most surgeons operate using

the concept of "tailored approach", which depends on the degree of preexisting oesophageal motility. That is both Nissen fundoplication in patients with normal oesophageal motility and Toupet fundoplication in reflux patients with poor oesophageal motility are associated with a low rate of dysphagia and an acceptable rate of recurrent reflux^(5,7,8). Some recent studies compared both procedures in patients with normal and abnormal oesophageal body motility. They abandoned this tailored concept since abnormal manometry cannot predict postoperative dysphagia and, on current evidence, "tailoring" the operation does not prevent its occurrence^(3,4,9). Furthermore, in single approach studies, the surgeons found that after Nissen fundoplication, similar postoperative heartburn, swallowing, and overall satisfaction were reported by patients with normal and abnormal oesophageal motility with equally low dysphagia rates⁽¹⁰⁻¹²⁾. Likewise, Toupet partial fundoplication was emphasized by others to be safe and highly successful therapeutic option as the primary repair in all GORD patients, independent of their oesophageal motility.

In view of the still controversial opinion regarding the tailoring concept of antireflux procedure, this prospective randomized study was done to evaluate the two operative techniques in terms of reflux control, dysphagia, acid exposure control on 24-hours pH monitoring and healing of oesophagitis, with the objective to determine the impact of preoperative normal and abnormal oesophageal motility on the outcome.

PATIENTS AND METHODS

From July 2000 to December 2002, GORD patients were randomized for Nissen or Toupet fundoplication at El-Menia University Hospital. Prospectively recorded data were collected for eighteen consecutive patients undergoing first time either laparoscopic or open fundoplication for uncontrolled GORD.

Eighteen patients with chronic symptomatic GORD of at least two years duration were included. There were 11 males and 7 females, with age ranged from 29 to 52 years. The decision to operate was taken after at least two months of extensive medical treatment. Patients were excluded from the study if they had history of previous upper abdominal surgery, histologically improved Barrett's oesophagus, severe oesophageal stricture, large or fixed sliding hernia, or Paraoesophageal or mixed hiatus hernia. Randomization was carried out at the time of admission to the study by giving each patient a number, starting from 1 until 18 patients with odd numbers underwent floppy Nissen fundoplication and those with even numbers underwent Toupet fundoplication.

All patients had symptoms of GORD, such as

heartburn, regurgitation and/or choking, dysphagia and epigastric pain. GORD was documented by endoscopy and/or by ambulatory 24-hour pH monitoring.

A) Preoperative Assessment:

Clinical Evaluation:

Heartburn was defined as any painful or burning sensation behind the sternum and/or subxiphoid region with or without relation to food intake and/or posture. Regurgitation was defined as any sensation of spontaneous eructation of gastrointestinal contents into the mouth or upper pharynx. Dysphagia was defined as an uncomfortable sensation of food sticking in the oesophagus after or while eating.

Clinical evaluation included: symptomatic assessment (heartburn, regurgitation, dysphagia, odynophagia, epigastric pain, choking or coughing, hematemesis and/or melena, and weight loss), past history (of antireflux medications and its effectiveness, other medications, concomitant diseases and previous operations), physical examination and laboratory investigations for assessment of fitness for surgery. Pre and postoperative symptoms including heartburn, regurgitation, and dysphagia were scored according to the De Meester score from 0 (none) to 3 (severe)⁽¹³⁾.

Radiological Study:

All patients had either, a gastrograffin or barium swallow examination before operation conducted in the erect, supine and trendelenburg positions. Attention was paid to the presence of a hiatal hernia, reflux, stricture, oesophageal shortening, the quality of peristalsis, and gastric emptying.

Upper Gastrointestinal Endoscopy & Biopsy:

Upper gastrointestinal fiberoptic endoscopy was performed within three weeks before surgery and at the 6th month postoperatively on the same visit for manometry and pH study. The endoscopic aspect of the distal oesophagus was evaluated carefully. The LOS competence, reflux oesophagitis and sliding hernia were noted. Reflux oesophagitis was defined by visible erosions in the squamous epithelium at the lower end of the oesophagus and was graded according to the Savary and Miller classification grading. The length of the sliding hernia was recorded as the distance between the squamocolumnar junction (SCJ) and the diaphragm. Sliding hernia was diagnosed when this length was equal or more than 2 cm⁽¹⁴⁾. Oesophageal biopsy specimens were obtained from the mucosal erosions at the lower oesophagus and in patients with no endoscopic evidence of oesophagitis, biopsy specimens were taken 2cm and 5cm above the SCJ⁽¹⁵⁾.

Oesophageal Manometry and Ambulatory pH Monitoring:

Standard stationary intraluminal oesophageal manometry and 24 hour pH monitoring were performed for all patients preoperatively in the medical department. Patients were fasted for 6 hours before the study and all medications affecting oesophageal motility were discontinued at least 2 days earlier, while proton pump inhibitors were stopped 5 days before the study. While normal resting LOS pressure average is 15 to 30 mmHg, a mechanically defective sphincter is defined by an average resting pressure of less than 6 mm Hg. Oesophageal dysmotility was defined as peristalsis of 50% or less and/or mean distal oesophageal pressure of less than 40 mmHg⁽¹¹⁾.

The reflux parameters were calculated, for the 24-hour data using a computerized analysis program. Data recording of less than 20 hours were excluded from the study. Reflux was considered pathological when the normal composite score is more than 22 and/or the oesophageal pH fell below 4 for 4% or more of the total recording time.

B) Surgical Procedures :

Surgery was performed laparoscopically in 14 patients and due to some technical difficulties, it was done by the conventional open technique in the remaining 4 patients.

a) Open:

The patients were placed supine on the operating table, the procedure was performed through a formal laparotomy by use of an upper middle line incision.

b) Laparoscopic:

The patient was placed on a modified fracture table in a steep reversed trendelenburg position with the back elevated at approximately 30 degrees. The legs abducted to 45° angle at the hips. The surgeon stood between the patient legs. The pneumoperitoneum was established at 13 to 15 mmHg using the veress needle. Access to the abdomen was obtained using five trocars. The optiview trocar is gained through a 10-mm incision that was made either at or 4 fingers above the umbilicus, according to the patient's built. A fanlike retractor is placed immediately substernal to elevate the left lobe of the liver off the hiatus. A third retraction port with endoscopic Babcock clamp is placed at the level of the umbilicus, in the left anterior axillary line. The right and left operating trocars are placed in the mid point between the camera port and subcostal margin in each side.

Procedure:

a) Common steps:

Both laparoscopic and conventional open procedures were performed with the same formal steps, aiming to

establish effective reflux control along with proper relaxation of the LOS, allowing for normal swallowing, bleching and vomiting. The common features of the procedures were:

-complete mobilization of the gastric fundus with division of some of the short gastric vessels.

-mobilization and repositioning of the abdominal oesophagus with reduction of any sliding hernia.

-posterior crural repair with two or three non absorbable stitches.

reconstruction of a tension free wrap. To ensure a tension free wrap, the portion of the fundus pulled behind the oesophagus should remain in place, even after releasing the forceps. This was seen when the retro- oesophageal window was large enough and the proximal stomach adequately freed from its surrounding attachments. If the stomach springs back to its native position, the procedure continued with the appropriate steps to eliminate this tension.

b) The reconstruction of the wrap:

were completed according to one of the following methods:

Nissen Fundoplication:

In this repair, the posterior portion of the proximal greater curvature is pulled behind the oesophagus, and the two edges of the stomach circumferentially encircle the oesophagus just above the GOJ. The wrap was 360° and 1.5-2cm length, and its both limbs were fixed anteriorly in one row with three sutures. Of which one passed through the anterior muscular wall of the oesophagus.

Toupet fundoplication:

A 270° wrap of 3 to 4 cm length was performed. The anterior aspect of the fundus was pulled through the retro-oesophageal window, and the wrap was made by placing four rows of sutures between each of the fundic flaps and the oesophagus in the extent between 10-o'clock and 2-o'clock positions in relation to the oesophageal circumference.

In both procedures, the medial flap was anchored to the right crura by two stitches. Suction drains were used for all patients. Most patients received clear fluids the first or second postoperative day and soft diet thereafter. Laparoscopic group were usually discharged on fourth or fifth postoperative day, while the laparotomy group on the sixth or seventh day.

c) Complications:

any complication that occurred during or after the operation was recorded such as: I) intraoperative: bleeding, vagal nerve injury, splenic injury or tear of the liver capsule. II) postoperative: early as pyrexia, vomiting or late as dysphagia, inability to blech and/or vomiting, early satiety or recurrence of the symptoms.

C) Follow Up:

postoperative clinical follow up was performed at one, three and six months using the same preoperative clinical questionnaire, and the newly or persistant complaints, such as dysphagia, inability to blech, gastric distention and early satiety or heart burn were recorded.

Endoscopy, together with radiological study, manometry and 24-hour pH monitoring were assessed on the last visit. The residual relaxation pressure of the LOS was recorded to identify the postfundoplication lower oesophageal sphincter relaxation. Recurrence was defined based on one or more of three main findings: frequent symptoms that require medical treatment, daily symptoms that require vigorous medical treatment, endoscopic appearance of erosions proximal to the SCJ, or 24-hour pH parameters suggestive of pathological reflux.

STATISTICAL ANALYSIS

SPSS windows (version 8) and Epi-info (version 6) software used for analysis of the data as follow: description of qualitative variables in the form of frequency and percentages. Chi square test was used to compare qualitative data with each other. P value probability ($P > 0.05$ -non significant test, $P < 0.05$ - significant test, $P < 0.01$ - highly significant).

RESULTS

The study was conducted in 30 months in the period between July 2000 and December 2002 and the last operation was done on June 2002. There were 11 (61.1%) males and 7 (38.9%) females with age ranged from 29 to 52 years. All patients were randomized to either Nissen or Toupet fundoplication (surgical groups) and stratified prospectively according to their oesophageal motility into normal and dysmotility groups (motility groups). Dysmotility (primary peristalsis of < 40 mmHg in amplitude) was found in four (44.4%) of the 9 patients who underwent Toupet fundoplication, and in three (33.3%) of the 9 patients who had Nissen fundoplication.

The most presenting symptoms were heartburn and regurgitation with high prevalence in both motility groups. Symptoms were present for an average of 5.1 years, ranges from 2 to 9 years. Table 1 summarises the prevalence of symptoms in all patients with reference to the severity of symptoms and the score of severity in the motility and surgical groups. There were no significant differences in

the prevalence and severity of heratburn and regurgitation between the groups, motility and surgical. Dysphagia was significantly higher (71.4% out of 7 vs 36.3% out of 11), and severe (1.7 vs 0.8) in patients with dysmotility than those with normal motility, but with no differences among the surgical groups.

BARIUM STUDY

The study was normal in 7 (38.8%) patients, and the most common finding was reflux of barium into the oesophagus in 6 (33.3%) patients. In 4 (66.6) out of these 6 patients the reflux was spontaneous in the upright position. Sliding hernia with a mean length of 4.2 ± 1.4 cm was recorded in 7 (38.8%) patients (Two patients showed reflux and hernia).

UPPER GASTROINTESTINAL

ENDOSCOPIC FINDINGS:

According to the Savary-Miller classification of oesophagitis, 3 (16.6%) patients had no endoscopic oesophagitis, grade I was defined in 1 (5.5%) patient, grade II in 4 (22.2%) patients, grade III in 8 (44.4%) patients and grade IV in 2 (11.1%) patients .

Table 2 shows these findings and the relationship of other upper gastrointestinal endoscopic findings to the degree of oesophagitis. There was no statistically significant difference in the findings of the upper gastrointestinal endoscopy between patients with and without dysmotility , also there was no difference between patients in both antireflux procedures

MANOMETRIC STUDY

Preoperative stationary manometry was performed for all patients. While in 16 (88.8%) patients it showed weak resting LOS pressure with a mean of 6.2 ± 3.2 ranges from 0 to 10 mm Hg, in 2 patients it was within average 17 and 19 mmHg, but with very low peristaltic amplitude and abnormal 24- hour pH metry. The residual relaxation pressure ranged from -2.0 to 3 mmHg with a mean of 0.26 ± 2.1 .

The oesophageal body peristalsis was impaired in 7 (38.8%) patients, all of them had very low distal peristaltic amplitude ranges from 17 to 30 mmHg with a mean of 23.5 ± 4.6 mmHg and only 5 had low percentage of transmitting peristaltic waves (Table 3).

The mean LOS pressure showed no significant difference between patients in Nissen and Toupet groups and also in patients in motility groups. The residual relaxation pressure was significantly higher in patients with normal motility, also patients in Toupet group.

24 - HOUR PH MONITORING

Two patients terminated the test before 15 hours and only data of 16 patients could be collected before surgery. In 14 (87.5%) of 16 patients the total time percentage of pH less than 4 ranged from 8 to 94 with a mean of 26.8 ± 9.8 and the composite score of Johnson and De Meester ranged from 32.6 to 482 with a mean of 134.4 ± 18.5 (Table 4). In the remaining 2 (12.5%) patients the total time percentage was zero, and the composite score was 0.9 in one patient and 1.4 in the other. Patients with impaired oesophageal body peristalsis showed significantly high mean values of 24-hour pH metry.

PERIOPERATIVE DATA

Operative

With the exception of the extent of the wrap, the two procedures were similar in reduction of the hiatal hernia, division of the short gastric vessels, narrowing of the oesophageal hiatus, and suture fixation of the wrap to the crus. The average time for open fundoplication was 130 ± 15.9 , ranged from 125 to 170 min, and for laparoscopic procedures it was 90 ± 19.4 (75-130 min). No significant difference in the operating time between Nissen and Toupet fundoplication.

Perioperative Complications

They were seen in 4 (22.2%) patients. One patient had vagal nerve injury and later on he developed dyspeptic symptoms without heartburn or regurgitation. Splenectomy was performed in one patient in the laparotomy group, in whom the spleen was injured during the division of the short gastric vessels. In one patient, bleeding from the short gastric vessels was easily controlled after conversion to open approach. Bleeding due to periesophagitis required conversion to open surgery in a fourth patient.

Oral Intake and Hospital Stay

The patients who underwent laparoscopic fundoplication were given oral liquids and solids much sooner than the open group (1 ± 0.5 days vs 3.4 ± 1.2 days). The laparoscopic group also had a significantly reduced mean length of hospital stay (2.7 ± 1.3 days vs open 5.1 ± 3.8 days).

FOLLOW UP

Early Follow -Up (1 & 3 months)

In the early postoperative follow up at 1 month, 13 (72.2%) of the patients were asymptomatic. 5 (27.8%) patients presented with early postoperative dysphagia, 3 in Nissen and 2 in Toupet groups but with no statistically significant difference and also there was no significant difference in its prevalence in relation to preoperative oesophageal motility. Three months later dysphagia resolved in one patient spontaneously. Four patients required oesophageal dilatation which was done once in

one patient and twice in the other three with good results.

Late Follow Up (6 months)

Clinical Evaluation

Late follow up showed good symptomatic relief in most (88.8%) patients. This was referred to as relief of symptoms or symptomatic improvement without medication. Clinical recurrence with heartburn and regurgitation was presented by two patients (11.2%), who underwent Toupet fundoplication (one in each motility group). The results of the 24 hour pH study in these two patients improved but yet were still above the normal range. The mean De Meester score for heartburn was reduced significantly in all patients irrespective to the technique performed and preoperative oesophageal body motility. For heartburn it decreased from 2.3 ± 1.1 (1 - 3) to 0.2 ± 0.02 (0 - 2), for regurgitation from 2.1 ± 0.6 (1 - 3) to 0.1 ± 0.01 (0 - 2) and for dysphagia from 1.2 ± 0.15 (1 - 3) to 0.1 ± 0.03 (0 - 1) (Table 5 a,b).

Upper gastrointestinal Endoscopic Findings:

Before surgery, 3 patients had no signs of oesophagitis. In these 3 patients and in 12 others, there was no endoscopic oesophagitis postoperatively. The remaining 3 patients; 1 with normal motility (Nissen) and 2 with dysmotility (1 Nissen and 1 Toupet) had postoperative improvement to grade I and they were symptom free, but still with elevated 24 hour pH parameters.

Manometric Study

Preoperative and postoperative manometry data were available for 15 patients only (Three symptom free patients refused to continue the manometric study): 9 in the normal motility group (5 Nissen and 4 Toupet) and 6 in the dysmotility group (2 Nissen and 4 Toupet).

a- Lower Oesophageal Sphincter

Oesophageal manometry showed a highly significant increase in the mean lower oesophageal sphincter pressure and the mean residual relaxation pressure in all patients compared with the baseline data. However, Nissen fundoplication resulted in greater increase in these 2 parameters than Toupet fundoplication ($p < 0.05$) in both motility groups. The postoperative mean values of peristalsis in the normal motility group showed non-significant changes in comparison to the preoperative data. In the dysmotility group, both techniques showed a significant improvement in the mean values of the peristaltic amplitude and the propagated peristalsis percentage of the distal oesophagus (Table 6 a & b).

b- 24-Hour pH Monitoring

Postoperative 24-hour pH monitoring data were available for only fourteen patients. All features of 24-hour pH monitoring improved significantly after antireflux surgery, independent of preoperative oesophageal motor

function or the procedure performed in ten patients; yet remained elevated in four which made the mean composite score not returning to normal (Table 7 a & b)

Table (1): Prevalence of symptoms in all patients with reference to the severity of symptoms and the score of severity in the motility and surgical groups.

Symptoms	Patients all groups (n=18)	% Out of the total	Surgical group			
			Nissen (n=9)		Toupet (n=9)	
			N (n= 6)	D (n= 3)	N (n= 5)	D (n= 4)
▪ Heart burn	▪ 16	▪ 88.5				
- Mild to moderate	- 6	- 33.3	*2.2±0.2	2.4±1.3	2.5±1.1	2.1±1.9
- Severe	- 10	- 55.5				
▪ Regurgitation	▪ 15	▪ 88.3				
- Mild to moderate	- 6	- 33.3	*2.2±0.6	1.6±0.1	2.3±0.1	2.0±1.1
- Severe	- 9	- 50				
▪ Dysphagia	▪ 9	▪ 50				
- Mild to moderate	- 6	- 33.3	*1.0±0.3	2.0±1.1	0.6±0.1	1.4±1.0
- Severe	- 3	- 16.6				
▪ Epigastric and/or retrosternal Pain	▪ 8	▪ 44.4				
▪ Bleching and /or bloating	▪ 5	▪ 27.7				
▪ Chocking and cough	▪ 3	▪ 16.6				
▪ Odynophagia	▪ 2	▪ 11.1				

N = normal motility D= Dysmotility * score in mean n = number

Table (2): Relationship of upper gastrointestinal endoscopic findings to the degree of oesophagitis.

Savary-Miller classification	Incompetent LOS		visible reflux		sliding hernia	
	Number	%	Number	%	Number	%
Grade 0	3	16.6	2	11.1	1	5.5
Grade I	1	5.5	0	0	1	5.5
Grade II	4	22.2	3	16.6	1	5.5
Grade III	8	44.4	7	38.8	5	27.7
Grade IV	2	11.1	2	11.1	2	11.1

Table(3): Preoperative Stationary manometric findings.

Resting LOS Pressure	Patients	Normal peristalsis		Impaired peristalsis	
		Number	%	Number	%
Weak	16	11	61.1	5	27.7
Normal	2	-	-	2	11.1
Total	18	11	61.1	7	38.8

Table (4): 24-hour pH monitoring in 14 patients

Parameters	Mean values
Composite score	134.4 ± 18.5
Total time percentage pH < 4	26.8 ± 9.8

Table (5a): Comparison of pre-and postoperative symptom severity in patients with normal motility

Symptoms (Score)*	Nissen fundoplication		Toupet fundoplication	
	Preoperative	Postoperative	Preoperative	Postoperative
Heartburn	2.2 ± 0.2	0.1 ± 0.01 ^{a1}	2.5 ± 1.1	0.3 ± 0.02 ^{b1}
Regurgitation	2.2 ± 0.6	0.0 ± 0.0 ^{a2}	2.3 ± 0.1	0.2 ± 0.01 ^{b2}
Dysphagia	1.0 ± 0.3	0.1 ± 0.08 ^{a3}	0.6 ± 0.1	0.0 ± 0.0 ^{b3}

Table (5 b) : Comparison of pre-and postoperative symptom severity in patients with dysmotility

Symptoms (Score)*	Nissen fundoplication		Toupet fundoplication	
	Preoperative	Postoperative	Preoperative	Postoperative
Heartburn	2.4 ± 1.3	0.0 ± 0.0 ^{a1}	2.1 ± 1.9	0.4 ± 0.01 ^{b1}
Regurgitation	1.6 ± 0.1	0.0 ± 0.0 ^{a2}	2.0 ± 1.1	0.4 ± 0.02 ^{b2}
Dysphagia	2.0 ± 1.1	0.4 ± 0.01 ^{a3}	1.4 ± 1.0	0.2 ± 0.1 ^{b3}

* Values in Mean

^{a1}P < 0.05; ^{a2}P < 0.01; ^{a3}P < 0.05 (all P values versus preoperative)

^{b1}P < 0.05; ^{b2}P < 0.05 ; ^{b3}P < 0.05 (all P values versus preoperative)

Table (6 a): Mean pre-and postoperative manometry values in patients with normal oesophageal body motility.

Symptoms (Score)*	Nissen fundoplication		Toupet fundoplication	
	Preoperative (n = 6)	Postoperative (n = 5)	Preoperative (n = 5)	Postoperative (n = 4)
LOS:				
Resting P.	4.9 ± 1.2	16.3 ± 6.3 ^{a1}	5.5 ± 2.2	13.3 ± 3.3 ^{b1}
RRP.	0.43 ± 0.1	3.1 ± 0.2 ^{a2}	0.7 ± 0.1	2 ± 0.03 ^{b2}
Peristalsis:				
Amplitude	61.6 ± 10.2	62 ± 15.2 ^{a3}	59 ± 8.3	58.5 ± 15 ^{b3}
Percentage	73.2 ± 12.0	72.3 ± 17 ^{a4}	78.9 ± 13	77.8 ± 16 ^{b4}

Table (6 b) Mean Pre-and postoperative manometry values in patients with abnormal oesophageal body motility

Symptoms (Score)*	Nissen fundoplication		Toupet fundoplication	
	Preoperative (n = 3)	Postoperative (n = 2)	Preoperative (n = 4)	Postoperative (n = 4)
LOS:				
Resting P.	8.8 ± 3.9	16.1 ± 3.9 ^{a1}	7 ± 3.3	11.3 ± 15 ^{b1}
RRP.	- 0.7 ± 0.1	3.4 ± 1.2 ^{a2}	0.5 ± 0.2	1.8 ± 16 ^{b2}
Peristalsis:				
Amplitude	25.4 ± 5.0	30.9 ± 8 ^{a3}	22.2 ± 6.3	28.3 ± 8 ^{b3}
Percentage	41 ± 7.0	43.8 ± 6.7 ^{a4}	25.7 ± 8.0	27.8 ± 6.3 ^{b4}

LOS Lower Oesophageal Sphincter,

P Pressure;

RRP Residual Relaxation Pressure

^{a1}P < 0.01; ^{a2}P < 0.01; ^{a3}P < 0.05; ^{a4}P < 0.05 (all P values versus preoperative)

^{b1}P < 0.01; ^{b2}P < 0.01; ^{b3}P < 0.05; ^{b4}P < 0.05

Table (7 a): Mean pre-and postoperative 24-pH values in patients with normal oesophageal body motility.

Parameters	Nissen fundoplication		Toupet Fundoplication	
	Preoperative (n=5)	Postoperative (n = 4)	Preoperative (n = 4)	Postoperative (n = 3)
Composite score	121.5 ± 20.1	21.9 ± 8.2 ^{a1}	60.9 ± 18	21.6 ± 5 ^{b1}
TTP pH<4	26.6 ± 6.1	3.9 ± 1.2 ^{a2}	12.7 ± 4.3	3 ± 1.3 ^{b2}

Table (7b): Mean pre-and postoperative 24-hour pH values in patients with abnormal oesophageal body motility.

Parameters	Nissen fundoplication		Toupet Fundoplication	
	Preoperative (n = 3)	Postoperative (n = 3)	Preoperative (n = 4)	Postoperative (n = 4)
Composite score	161.1 ± 36	26.6±2.3 ^{a1}	156.9±25	23.5 ± 3.6 ^{b1}
TTP pH<4	28.8±9.9	3.75±1.1 ^{a2}	30.1 ± 10.2	3.5±2.1 ^{b2}

TTP Total Time Percentage

^{a1} P < 0.01; ^{a2}P < 0.01 (all P values versus preoperative)

^{b1} P < 0.01; ^{b2}P < 0.01 (all P values versus preoperative)

DISCUSSION

For some years now, upper gastrointestinal endoscopy, oesophageal manometry and pH study have formed part of the work up of GORD patients being considered for fundoplication supposedly (i) to ensure that the diagnosis of GORD is correct, (ii) to allow surgery to be tailored according to preexisting oesophageal motility, and (iii) to obtain preoperative data so that the success of treatment can be appraised from postoperative measurements in the same patient ⁽¹⁶⁾.

A variety of antireflux operations exist for patients with GORD. However controversy exists with regard to the choice of operation between complete 360° Nissen fundoplication versus partial 270° Toupet fundoplication. Nissen fundoplication is used very frequently but it has a relatively high incidence of wrap related complications such as bloating, inability to belch, and dysphagia. Partial wrapping has been reported to be equally effective but associated with fewer unfavourable postoperative symptoms^(5,6). In addition there is some controversy with regard to the proper choice of operation in patients with poor oesophageal motility. Most surgeons operate using the concept of “tailored approach”, which depends on the degree of pre-existing oesophageal motility. That is both Nissen fundoplication in patients with normal oesophageal motility and Toupet fundoplication in reflux patients with poor oesophageal motility are associated with a low rate of dysphagia and an acceptable rate of recurrent reflux ^(5,7).

Some recent studies compared both procedures in patients with normal and abnormal oesophageal body motility. They abandoned this tailored concept since abnormal manometry cannot predict postoperative dysphagia and, on current evidence, tailoring the operation does not prevent its occurrence ^(3,17).

Furthermore, in single approach studies, the authors found that after Nissen fundoplication, similar postoperative heartburn, swallowing and overall satisfaction were reported by patients with normal and abnormal oesophageal motility with equally low dysphagia rates ^(11,12). Likewise, Toupet fundoplication was emphasized by others to be a safe and highly successful therapeutic option as the primary repair in all GORD patients, independent of their oesophageal motility ^(4,6).

In view of the still controversial opinions regarding the tailoring concept in the management of GORD, this prospective randomized study was done to evaluate the two operative techniques in terms of reflux control, dysphagia, acid exposure control on 24-hour pH monitoring and healing of oesophagitis, with the objective to determine the impact of preoperative normal and abnormal oesophageal motility on the outcome, following floppy Nissen versus Toupet fundoplication.

The most common symptom of GORD is heartburn. Regurgitation is another common symptom. When present together, heartburn and regurgitation are highly predictive of acid exposure to the oesophageal mucosa, and establish

the diagnosis of GORD with more than 90% certainty⁽¹⁸⁾. In a prospective study of 228 patients with GORD, Eubanks and colleagues found that the prevalence of heartburn was 85% and of regurgitation was 51%. They found the primary symptom in 75% of the patients was heartburn and it was recorded as the second most bothersome symptom in 50% of the remaining cases⁽¹⁹⁾. In another study of 103 patients with GORD, the prevalence of heartburn and regurgitation among these patients was 92% and 40% respectively⁽²⁰⁾. In this study, the prevalence of heartburn (88.8%) corresponded with the above studies, but for regurgitation (83.3) was greater and this variation may be due to the fact that regurgitation and dysphagia are often not reported or recognized by patients earlier owing to modification of diet or eating habits⁽²¹⁾.

Excluding patients with an oesophageal stricture, difficulty in swallowing occurs frequently with reflux disease, in 20-50% of patients before antireflux surgery⁽²²⁾. In this study, 9 (50%) patients complained of dysphagia, a figure that is consistent with these studies, but these results greatly differ from what is reported by Staff et al. in a retrospective study. They found an incidence of dysphagia of 3% in 29514 patients without stricture or ulcerative oesophagitis, and 13% in 5064 patients with these complications⁽²³⁾.

Regarding the effect of oesophageal body motility on the symptoms in patients with GORD in this study, there were no significant differences in the prevalence and severity of heartburn and regurgitation between patients with normal motility and those with hypomotility, but dysphagia was higher and more severe in the dysmotility group. These findings are constant with what was reported by other comparative randomized studies^(4,9).

Peptic oesophagitis is the commonest endoscopic diagnosis being found in 25% of patients having an upper gastrointestinal endoscopy⁽²⁾, but only one-third to one-half of patients with GORD undergoing endoscopy have oesophagitis as assessed by current endoscopic techniques⁽¹⁾. However, Quigley in 2001 reported that 60% of patients with GORD do not have detectable evidence of oesophagitis and they can be classified as having non-erosive or negative endoscopy reflux disease (NERD)⁽²⁴⁾, a condition that was found in only 3 (6.67%) patients in this study. According to the Savary-Miller classification of oesophagitis, in this study 3 (16.6%) patients had no endoscopic oesophagitis, grade I was defined in 1 (5.5%) patient, grade II in 4 (22.2), grade III in 8 (44.4%) and grade IV in 2 (11.1%). Bais et al. in their study on 99 patients, they represented the following results according to the endoscopic findings: no oesophagitis in 55 (55%) patients; grade I in 31 (31%); grade II in 10 (10%); grade III in 2 (2%) and; grade IV in 1 (1%)⁽²⁰⁾. Another range of endoscopic results was reported by Zoring et al., they found (26%) patients have no endoscopic findings, (39%)

patients with grade I, (26%) with grade II (6.5%) with grade III and (2.5%) with grade IV⁽⁴⁾. This variation in results among studies depends greatly on the time the patient referred to the endoscopist; that is the majority of patients seek treatment regularly using over the counter antireflux products before endoscopy⁽¹⁸⁾.

Impaired oesophageal body motility is a common finding in GORD, with a prevalence of 25% in patients with mild disease and up to 50% in patients with severe disease⁽²⁵⁾. In this study, 7 (38.8%) patients had a low oesophageal body peristaltic pressure of less than 30 mm Hg. Of the 18 patients in this study, 16 (88.8%) showed preoperative weak resting LOS pressure in both motility groups without significant differences. While these findings are consistent with what was represented by Beckingham et al.,⁽¹¹⁾ they are in contrast with what was described by Fibbe et al., who reported that patients with oesophageal dysmotility had significantly more sphincter incompetence than those with normal oesophageal motor function⁽³⁾.

In contrast to Beckingham et al.,⁽¹¹⁾ and Fibbe et al.,⁽³⁾ who reported no significant difference in the preoperative mean values of 24-hour pH metry between the normal and hypomotility groups, this study and another prospective studies, recognized an obvious difference in the pH values regarding oesophageal motility^(26,27). We found that patients with impaired primary oesophageal body peristalsis had greater acid exposure.

Several published trials compare open with laparoscopic surgery, claim an increase in postoperative dysphagia with the latter⁽²⁸⁾. This is also supported by the results of a multicentre randomized controlled trial of 103 patients, which show a significant difference in dysphagia rate at 3 months (open 0%, laparoscopic 12%)⁽²⁰⁾. Some factors were suggested to explain the higher incidence of dysphagia after laparoscopic surgery. These include greater oesophageal trauma owing to impaired tactile feedback, less fundal mobilization, especially with non-division of short gastric vessels and spatial differences resulting in the creation of a smaller posterior window⁽²⁸⁾. With the exception of some operative complications such as splenic and vagal nerve injury in the open approach, there were no significant differences in outcome among the open and laparoscopic groups in this study.

The rationale for performing a partial fundoplication is to reduce the resistance to bolus transport noted after a total fundoplication, thus reducing the risk of dysphagia⁽²²⁾, but there is some concern that with longer follow-up, partial fundoplication procedures fail to control reflux adequately⁽⁹⁾. However, the original Nissen fundoplication was 4-6 cm long and snug around the oesophagus⁽²⁹⁾, De Meester and Stein introduced the concept of a short floppy fundoplication to overcome the worse effect of a long tight

wrap⁽³⁰⁾. However, recent studies showed that tailoring antireflux surgery to oesophageal motility is not indicated, since motility disorders are not correlated with postoperative dysphagia⁽⁴⁾. Heider et al., emphasized that Nissen fundoplication significantly improve preoperative dysphagia and result in no or less new dysphagia in both types of patients⁽¹²⁾. In this study patients were divided randomly in 2 equal groups independent of oesophageal body motility, one group underwent floppy Nissen fundoplication and the other one operated with Toupet (270°) fundoplication.

There are increasing recognitions of the importance of the diaphragmatic crura in the antireflux mechanism, especially during inspiration and straining⁽³¹⁾. Despite this, many surgeons have elected to forego hiatal repair during laparoscopic procedures, resulting in an incidence of up to 10% of wrap herniation or paraoesophageal herniation with recurrent reflux or dysphagia⁽³²⁾. However, closing the hiatus also may contribute to postoperative dysphagia⁽³³⁾. It is suggested that part of the problem is related to oesophageal angulation created by a long posterior repair⁽²⁷⁾. In this study like many recent studies, all procedures were performed with posterior crural repair^(9,27). In this study, all procedures were performed without bougie and in Nissen fundoplication the wrap was 1.5 to 2, while in Toupet procedure it was 3 to 4 centimeters. Bassell et al., in their study of Toupet fundoplication, they proposed the same wrap length⁽³⁴⁾. Some studies reported that although oesophageal dysmotility may affect the symptoms of the disease, it did not affect the outcome after either Nissen or Toupet fundoplication in that improvement and relief of heartburn and regurgitation as well as reflux control on 24-hour pH monitoring and healing of oesophagitis were similar in patients with both normal and abnormal oesophageal motility^(3,4,9). In their studies as well as in this study, the short term outcome measures for Toupet and Nissen antireflux procedures based on symptom relief or improvement without medication reported a success rate of 84% at short term follow-up (around the 6th month) independent of oesophageal motility or the procedure performed. GORD recurrence (clinical, endoscopic and/or pH studies) in this study (23%) was unrelated to preoperative oesophageal motor function. This is consistent with what was found by Fibbe et al., At 6 months follow-up, they established that 35 (17.5%) patients (15 Toupet, 20 Nissen) had GORD recurrence: 14 of 100 patients with normal (4 Toupet, 10 Nissen) and 21 of 100 patients with abnormal oesophageal motility (11 Toupet, 10 Nissen)⁽³⁾.

In two comparative studies, although significantly more patients with preoperative dysphagia had abnormal motility on manometric studies than those without, postoperative dysphagia was unrelated to preoperative oesophageal motor function but was dependent on the type of fundoplication, that was more frequent following a

Nissen fundoplication than after a Toupet^(3,4). In contrast to these results, Fernando et al., found that both operations brought acid reflux to within normal limits, but dysphagia improves significantly after Nissen fundoplication⁽⁹⁾. In this study, results showed greater number of patients with dysphagia after Nissen than Toupet (3 Nissen versus 2 Toupet) but this difference was not statistically significant. Four patients required postoperative oesophageal dilatation.

Oesophagitis usually improves significantly after either procedure, Nissen or Toupet, early in the postoperative period^(3,4). This is consistent with this study findings. Although 3 patients in the dysmotility group still had grade I oesophagitis after surgery, there was a significant improvement in endoscopic presentation of mucosal injury, which were similar in both motility groups and no variations existed between the 2 antireflux procedures.

Both Nissen and Toupet fundoplication significantly increased postoperative LOS pressure and its residual relaxation pressure, with a more pronounced effect after Nissen fundoplication, but with non statistically significance and with poor correlation to postoperative dysphagia. Comparative studies agree with a significant increase in these 2 parameters after both techniques, but the relation between postoperative dysphagia and this pressure increment after total fundoplication still controversial^(3,4). However, others proposed that patients with a normal LOS or high mean LOS pressures are at increased risk for developing this complication and should be informed of this before laparoscopic Nissen fundoplication.⁽³⁵⁾

Despite the significant improvement, oesophageal contraction amplitude and peristalsis percentage in this study return to normal values only in 3 cases. Some authors observed an improvement in these 2 parameters after either procedure, but Nissen not Toupet produced a significant increase in amplitude of oesophageal peristalsis^(4,9).

In this study, symptomatic outcome was compared to postoperative pH testing at short-term follow-up to determine the accuracy of clinical assessment at predicting whether acid exposure would be normal or abnormal. Mean values (total time percentage, pH < 4 and DeMeester score) of acid exposure in the distal oesophagus were reduced significantly in all patients without significant variation between either antireflux technique in both motility groups. The postoperative mean DeMeester score was 21.9 ± 8.2 in patients with Nissen versus 21.6 ± 5 in those with Toupet fundoplication in the normal motility group ($P > 0.05$) and 26.6 ± 2.3 in Nissen versus 23.5 ± 3.6 in Toupet in the dysmotility group ($P > 0.05$). Other studies agree with that but they observed that Nissen procedure more pronounced to normalize acid exposure than Toupet^(9,19)

CONCLUSION

In conclusion, symptoms and objective acid exposure measurements are improved significantly by either Nissen or Toupet antireflux procedures at short-term follow-up. Symptom assessment is an adequate, although not perfect, outcome measure for antireflux procedure. Heartburn is the most reliable symptom to predict acid reflux in the postoperative period. Patients with persistent symptoms of heartburn should be assessed with postoperative pH testing.

Although oesophageal dysmotility may affect clinical symptoms of the disease, it did not affect the outcome after either Nissen or Toupet fundoplication, so preoperative abnormal manometry cannot predict postoperative dysphagia and on current evidence, tailoring the operation to the preexisting oesophageal motility does not prevent its occurrence. Further studies are needed to assess these findings.

Finally floppy Nissen fundoplication or Toupet fundoplication is a good therapy in an appropriate clinical setting when performed by a well trained and experienced surgeon. However, the operation should not be first line therapy for the majority of GORD patients. An oesophagus disabled by an inappropriate or dysfunctional fundoplication wrap is a terrible price to pay for control of acid reflux.

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