

Original Research Article

Laparoscopic floppy Nissen fundoplication: evaluation of outcome in 34 patients operated without prior oesophageal pH and manometry

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ABSTRACT

Background: Aim of the study was to evaluate prospectively the outcomes of laparoscopic floppy Nissen fundoplication in cohort of patients with typical symptoms of gastroesophageal reflux disease (GERD) and hiatus hernia without pre-operative 24 hours oesophageal pH and manometry study.

Methods: Thirty-four patients with typical symptoms of GERD, from March 2009 to November 2019, were studied. The study was limited to patients with positive findings on upper GI endoscopy done by operating surgeon with typical symptoms (heartburn, regurgitation, and dysphagia) of GERD and hiatal hernia. Laparoscopic Nissen's fundoplication was performed when clinical assessment suggested adequate oesophageal motility and length. Only 1 patient, who had negative endoscopic findings, underwent a 24-hour pH-monitoring before surgery. Outcome measures included assessment of the relief of the primary symptom responsible for surgery in the early postoperative period; the patient's evaluation of outcome and quality of life after surgery.

Result: Laparoscopic Nissen's fundoplication is an effective long-term treatment for GERD and may be performed in patients with typical symptoms of GERD and hiatus hernia and endoscopic findings suggestive of reflux esophagitis and patient who wants to get rid of life long proton-pump inhibitors (PPI) and antacids medication.

Conclusions: Preoperative oesophageal manometry and 24-hour pH monitoring are not mandatory for laparoscopic fundoplication if the patient selection is appropriate but may be required in selected patients with atypical symptoms.

Keywords: GERD, Laparoscopic floppy Nissen fundoplication, Hiatus hernia, Oesophageal pH and manometry

INTRODUCTION

Aim of the study was to evaluate retrospectively the outcomes of laparoscopic floppy Nissen fundoplication in cohort of patients with typical symptoms of gastroesophageal reflux disease (GERD) and hiatus hernia without pre-operative 24 hours oesophageal pH and manometry study.

GERD is a condition that causes irritation and injury of oesophageal mucosa due to the regurgitation of acidic stomach contents into oesophagus. This backwash (acid reflux) can irritate the epithelial lining of oesophagus

leading to typical and atypical symptoms and if the pathological process continues, Gastroesophageal reflux becomes a chronic phenomenon that usually requires long-term medical therapy with the risk for oesophageal stricture, Barrett's oesophagus and oesophageal cancer while significantly affecting health-related quality of life and work productivity. An alternative treatment is anti-reflux surgery that manage the discomfort of GERD with lifestyle changes. Hence development of laparoscopic fundoplication over the past several years has resulted in renewed interest in surgical management of GERD. It is safe, effective with overall patient satisfaction in long term follow up.

Quality of life analyses has now become an important part of surgical outcome analyses with regular follow up.

Since Rudolf Nissen's original fundoplication in 1937, performed to protect a GE anastomosis, The Nissen fundoplication has undergone many modifications.¹

The principals of modern Nissen fundoplication are designed to most closely replicate the normal physiology of the gastroesophageal flap valve including secure rural closure and creation of short 360-degree floppy wrap around 2 to 3 cm of intrabdominal oesophagus.

METHODS

The present study includes 34 study subjects. Study design included the prospective observational study. The study was conducted for a period of 10 years from March 2009 to March 2019.

Data was collected prospectively for the study. All patients had their required investigations done on admission. The study was approved by the Institutional Ethics Committee (IEC) of SMIMER medical college. Studied 34 patients out of which 28 were male and 6 females, in Dept. of Surgery, SMIMER hospital, Surat from 2009 to 2019 with typical complains of GERD like heartburn, regurgitation and other typical GERD symptoms. All patients came from lower socioeconomical class. Among these 90% of the patients has regurgitation with reflux, 80% had heart burn. All patients were used to take PPI for relief but not satisfied. All patients were investigated by upper GI endoscopy (Oesophagus-gastroduodenoscopy) prior to surgery by operating surgeon himself. All patients were investigated by all routine blood investigations, chest X-ray followed by pre anaesthetic check-up for fitness. Also done barium swallow in all patients to confirm hiatus hernia, motility disorders and oesophageal shortening. All patients with typical symptoms of GERD with confirmed signs of Reflux Oesophagitis and Hiatus hernia on Esophago-gastroduodenoscopy (OGD) and no signs of oesophageal shortening and mortality disorder on barium swallow examination were selected for Laparoscopic floppy Nissen Fundoplication. In SMIMER hospital set up, 24 hours pH monitoring and manometry facility is not available so after counselling 4 patients with atypical symptoms and no sign of reflux oesophagitis on OGD, were send outside for 24-hour pH monitoring which revealed their De-meester score between 22 to 43. All patients were operated for laparoscopic floppy Nissen's fundoplication after anaesthetics and physician fitness.

Inclusion criteria included patients who were documented oesophageal injury as per Los Angeles classification system grades reflux esophagitis.² All patients of hiatus hernia, willing for surgical management and Patients not willing for life long PPI.

Exclusion criteria was- not fit for general anaesthesia, Previous upper abdominal surgery, Unfavourable features like oesophageal stricture (may be neoplastic) and Patients suspected for serious motility disorder on clinical evaluation and UGI endoscopy.

Preoperative workup

The aim of preoperative investigations is to select the appropriate patients having reflux and hiatal hernia for surgical treatment in order to optimize outcomes. There is currently no consensus and significant variability among surgeons regarding which studies should be obtained before surgery and in what order.

EGD: Is likely the one study that all patients should undergo preoperatively, as it can confirm the diagnosis of GERD or identify other aetiologies of esophagogastric mucosal abnormalities and allows biopsies to be taken. In patients, 10 patients had 3-5 cm size hiatus hernia, 21 patients had 6-8 cm size hiatus hernia and 3 patients had >8 cm size hiatus hernia on UGI endoscopy.

According to Los Angeles classification 19 patients were in grade A, 13 patients in grade B, 2 patients in grade C,

Barium swallow: Obtained in all cases for better delineation of the anatomy. May be particularly important to diagnose oesophageal shortening and motility disorders.

Operative steps

The procedure is carried out using general anaesthesia with the patient in the low lithotomy (or legs apart) with reverse Trendelenburg position. The surgeon stands in between the legs, and the assistant holding the camera stands on the right of the patient; and the other assisting surgeon, on the left. Pneumoperitoneum is produced using a veress needle introduced through a small supraumbilical incision. After placing 11 mm supraumbilical trocar for camera, place remaining working trocars under vision. Right hand working port (11 mm) is placed in left midclavicular line 5 cm above the level of umbilicus and left hand working port (5.5 mm) is placed 2-3 cm medial to right midclavicular line approx. 5 cm above the level of umbilicus. The accessory port 5.5 mm is placed in anterior axillary line left subcostal region for retraction of stomach. All the ports are ergonomically positioned under vision to make sure that the distance between hiatus and working port is 10 to 15 cm (Figure 1).

The stand of Nathanson's retractor is fixed on left railing of OT table and appropriate size Nathanson retractor according to size of left lobe is placed in the high of epigastrium. Left lobe is retracted in such a way that anterior hiatus is visible. After placing all trocars, the first steps of procedure are to divide the peritoneum in front of the caudate lobe with ultrasonic harmonic scalpel,

dissection proceeds superiorly exposing the right crus of diaphragm.

Next dissection is started from medial side of right crus of diaphragm and peritoneum lateral to oesophagus is opened but peritoneum over right crus of diaphragm is preserved (Figure 2). Dissection is extended anteriorly till phreno-oesophageal ligament is divided. Oesophagus is dissected from right to left preserving right vagus nerve till anterior surface of left crus is visible. Peritoneum lateral to Left crush is opened and upper half of stomach is mobilised completely after division of short gastric vessels with harmonic scalpel (figure 3). Any attachment behind stomach is divided.

The oesophagus is elevated, and the posterior vagus nerve can be identified easily behind the oesophagus. Both are lifted, and posterior window is created. Great care should be exercised in making this opening under clear vision without damaging the posterior wall of the stomach or oesophagus. An umbilical tape is passed posterior to the oesophagus to help in retraction. Then circumferential dissection of Oesophagus is completed avoiding injury to right and left pleura and anterior vagus to achieve at 3-4 cm length of lower oesophagus inside the abdomen.

Crurorraphy is done by ethibond 1-0 interrupted suture without impinging oesophagus. Fundus is delivered from left to right behind oesophagus and shoes lace manoeuvres is done to check adequacy of fundal mobilization (figure 4). Floppy Fundoplication is done by taking 3 sutures, upper suture fundus to fundus, middle passing from fundus, oesophagus, fundus and lower passing from fundus to fundus by ethibond 3-0. Floppiness of wrap is checked by passing instrument between oesophagus and fundal wrap so that under surface of diaphragm is visible (figure 5).

At last, upper GI scopy is done to check floppiness of fundoplication and Nipple Sign which suggest ideal fundoplication(fig6). During retraction of liver 4 patients had minor liver injuries but it was managed by local pressure without need of blood transfusion. Three patients had intra operative pneumothorax due to pleural injury on left side and on right side in one patient. In one patient inter costal drainage tube was inserted while rest two patients did not require ICDT insertion. No any major intra operative complications or conversion were noted in our study.

All patients mobilised after 8 hours of surgery and Ryle's tube was removed on 1st postoperative day in morning, liquid diet was started after 24 hours, patients were allowed for soft diet after 48 hours, full diet after 72 hours. Patients were discharged with proper counselling to chew the food well and eat small meals and aware about aerophagia and unable to belch. Prescribed PPI and syrup simethicone for 15 days. Followed up patients at the end of 1st week ,1st month and 6-month,1 year and

then after yearly for 10 years (initial few patients). Data on operative time, period of hospitalization, and complications were collected for all patients. Outcome measures included assessment of the relief of the primary symptoms responsible for surgery in the early postoperative period; the patient's evaluation of outcome and quality of life after surgery



Figure 1: Port placement.



Figure 2: Dissection between right crus and oesophagus.



Figure 3: Division of short gastric vessels.

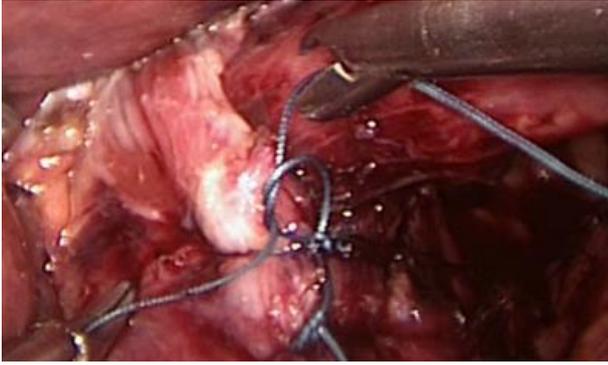


Figure 4: Completion of cruroraphy.

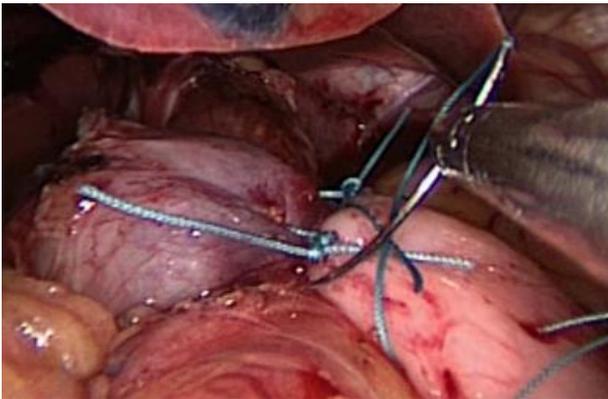


Figure 5: Fundoplication near completion.



Figure 6: Nipple sign on OGD after surgery.³

RESULTS

Studied 34 patients in SMIMER hospital, Surat surgery department from 2009 to 2019 with typical GERD symptoms and hiatal hernia. The average age of the patient is 32 ± 2 years (Table 1). Upper GI endoscopy was done in all patient and laparoscopic floppy Nissen fundoplication was done. All 34 patients, all were on regular follow-up on an outpatient basis. All patients had mild dysphagia which resolved in 1 week. 4 patients had bloating for 1 month. On 6 months follow up all patients were symptoms free without PPI and syrup. All 4 patients who has bloating, UGI endoscopy was done after 1

month, all patients had positive urease test for *H. Pylori* so *H. pylori* eradication kit was given for 15 days with satisfactory result.

Epigastric pain and dysphagia were present in all patient in preoperative and in few patients, 48-72 hours after surgery and two patients after discharge. Similarly, heart burn and reflux were present in preoperative period, out of which heart burn was occasionally present after discharge, but reflux symptoms were not present after discharge (Table 3). Anti-reflux medication like PPI was given till one month after the surgery to 23 patient and for 3 months to 6 patient and for 1 year to 2 patients (Table 2). Prokinetics was given for 1 month to 11 patients after surgery, and for 3 months to 2 patients and none of the patients require prokinetics after 6 months of surgery. 32 patients were cured of typical symptoms while 2 patients were satisfied with surgery but required medication for symptomatic relief.

The overall short-term result in appropriately selected patients are excellent. 14.7% had transient dysphagia due to post-operative oedema secondary to surgical manipulation of gastroesophageal junction, 17.67% has epigastric pain, which Improved within 6 weeks and after one year only 2 patient has epigastric discomfort which was managed by medical therapy.

6 patients operated between 2009-2010, yearly follow up for 10 years demonstrate excellent procedure satisfaction, symptoms relief, improved quality of life and cessation of acid suppression therapy. Overall, in long term follow up, 32 patients (94%) were cured and were off acid suppression therapy. and 2 patients (5.8%) satisfied with the surgery along with PPI continuation. One female patient on 5 year follow up developed cholelithiasis, which was managed by laparoscopic cholecystectomy. In this study none of the patient required revision of the surgery suggestive of proper surgical procedure followed.

In this study found that GERD is associated with significant discomfort to the patient both related to typical (heartburn, regurgitation and dysphagia) and atypical (cough, hoarseness and wheezing) symptoms and that quality of life improves significantly following laparoscopic floppy Nissen fundoplication. Moreover, found that the dynamics of quality of life improvement are different for different aspects of quality of life and different for different individuals. Epigastric pain was observed in virtually all patients prior to surgery, and the duration of the pain was on average nearly 8-10 years. Typical symptoms are more reliable and precise guide to the presence of disease.

Result of the study is depicted in tabular and chart form.

Youngest patient was 18-year female and oldest was 54-year male with mean age of 34 ± 2 years.

Table 1: Age wise distribution (n=34).

Age (years)	No. patients
15-30	04
30-40	14
40-50	12
50-60	04
Youngest patients	18, Female
Oldest age	54, Male
Mean age	32 ± 2

Table 2: Anti reflux medication before and after surgery.

Medication	Pre-op	6 months Post-op	12 months Post-op
PPI	34	4	2
H2 blocker	10	2	0
Antacids	2	0	0
Calcium channel blockers	1	0	0
Antianxiety drugs	1	0	0
Prokinetics	1	0	0

Table 3: Disease specific question.

Symptoms	Pre-op	48-72 hr of post-op time (%)	After 1 year
Epigastric pain	Yes	Yes (6/34) 17.67	02
Heart burn	Yes	No	No
Reflux	Yes	No	No
Dysphagia	Yes	Yes (5/34) 14.7	No

Only 6 patient has epigastric pain in the postoperative period of 48-72 hours. 5 patient has dysphagia in the post-operative period of 48-72 hours.

Table 4: Patient's assessment of outcome at 1 year.

Quality of life	No. of patients
Cured	32
Satisfied with surgery (avg. outcome, persistent GERD therapy required)	02

DISCUSSION

It is well known that manometry gives an idea about the propulsive force of the body of the oesophagus. Oesophageal manometry assessed the, length, location, and pressure of the LES (Lower oesophageal Sphincter), along with its ability to relax during swallowing. In addition, it also allows proper placement of the probe for ambulatory pH monitoring. But oesophageal manometry was mostly useful for positioning the pH probe and rule out achalasia cardia.⁴

Ambulatory pH monitoring is the gold standard test for the diagnosis of GERD, with a sensitivity and specificity of about 92%. It is of key importance in the workup for the following reasons. Ambulatory pH monitoring is the only way to quantitatively express the overall degree and pattern of oesophageal acid exposure, both of which may impact the decision towards surgery. It gives an idea about abnormal reflux. In the UCSF (University of California, San Francisco) study pH monitoring yielded normal results in 30% of the patients, with a clinically proven diagnosis of GERD, thereby obviating the need for the continuation of PPIs or the performance of an ant reflux surgery.⁵

Typical symptoms are a more reliable and precise guide to the presence of disease, and consequently their improvement better reflects the effectiveness of therapy and the decision of laparoscopic fundoplication.

However, study conducted by Anish P Nagpal et.al in Analysis of 46 consecutive patients concluded Although oesophageal manometry and 24-hour pH-monitoring might be necessary with abnormal findings on video fluoroscopy or atypical symptoms, their routine use is not essential in preoperative evaluation of patients undergoing fundoplication for gastroesophageal reflux disease.⁶

In another study conducted by Kapadia et.al, role of preoperative high-resolution manometry in predicting dysphagia after laparoscopic Nissen fundoplication it was concluded that No significant association was demonstrated between preoperative HRM (high resolution manometry) parameters and surgical outcomes.⁷

Even in absent oesophageal peristalsis, is not a contraindication to laparoscopic Nissen fundoplication and is supported in a study, conducted in 48 patients with severe oesophageal dysmotility who underwent Laparoscopic Nissen's fundoplication and this evidence is further supported by Novitsky et al who concluded that GERD patients with dysmotility can undergo a well-constructed total fundoplication without risk of dysphagia since multiple reports showed that elimination of acid exposure improves oesophageal motility and oesophageal clearance.^{8,9} The authors also explain that oesophageal dysmotility is a known sequel of chronic oesophageal acid exposure rather than a pre-existing condition.

In one study conducted by Broeder's JA long with 10 year follow up of laparoscopic Nissen fundoplication revealed that 92.5% of patients were satisfied with the result of Surgery 90% had durable improvement of their symptoms, 70% of patient were off acid suppression therapy. 8.3% were require revision surgery.¹⁰

According to society of SAGES following patients are suitable for laparoscopic fundoplication: Patients who have failed medical management (inadequate symptom

control, severe regurgitation not controlled with acid suppression, or medication side-effects), patients who opt for surgery despite successful medical management, patients who have complications of GERD (e.g., Barrett's oesophagus, peptic stricture) and Patients who have extra-oesophageal manifestations (asthma, hoarseness, cough, chest pain, aspiration).

According to AGA following patients are suitable for laparoscopic fundoplication patients with esophagitis who are intolerant of PPI therapy, patients with symptoms of the oesophageal GERD syndrome poorly controlled by PPI therapy, especially in the setting of persistent troublesome regurgitation, and Carefully selected patients with extraoesophageal GERD syndromes in whom a reflux causality has been established to the greatest degree possible.

The diagnosis of GERD provides the identification of patients with oesophagitis and its complications, as well as patients who have symptoms but no mucosal disease. Endoscopy is mandatory to establish a diagnosis of reflux oesophagitis, to exclude other oesophageal disease and to take biopsy if malignancy is suspected. Measures of oesophageal acid exposure time may be used to quantify reflux before and after treatment; however, if the patient has typical symptoms but no oesophagitis, a temporal association between symptoms and episodes of oesophageal acidification should be sought. Ambulatory 24-hour oesophageal pH-monitoring with accurate event-marking provides recordings suitable for an objective statistical analysis, which was done in only 1 patient, who had typical symptoms of GERD but negative endoscopic findings. Although oesophageal manometry and 24-hour pH-monitoring might be necessary with abnormal findings on upper GI scopy or atypical symptoms, their routine use is not essential in preoperative evaluation of patients undergoing fundoplication for gastroesophageal reflux disease.

CONCLUSION

Laparoscopic fundoplication is an effective long-term treatment for GERD and may be performed in patients with typical symptoms of GERD and hiatus hernia and endoscopic findings suggestive of reflux esophagitis and patient who wants to get rid of life long PPI and antacids medication. Preoperative oesophageal manometry and 24-hour pH monitoring and manometry is not mandatory for laparoscopic fundoplication if the patient selection is appropriate but may be required in selected patients with atypical symptoms.

Limitations of the study

It's a single centre, single surgeon performed procedure study so no control groups available for comparison and

the result is totally based on the outcomes and performances of the patients in regular follow ups.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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