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Role of Laparoscopic Fundoplication in the Management of Gastro-Esophageal Reflux Disease: An Evidence-based Appraisal

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Abstract

Gastro-esophageal reflux disease (GERD) is a very common medical disease. There is no consensus for optimal management of GERD. Proton pump inhibitors (PPI) are the most effective drug treatment for GERD. The number of antireflux procedures is on the rise, partly due to increased patient's expectations, and partly due to the advancements in minimal access surgery. There are few controversies surrounding role of laparoscopic fundoplication in the management of GERD, like whether surgery is superior to PPI; which modality is better, laparoscopic or open; whether complete wrap is better than partial, and whether division of short gastric vessels provides any advantage or not. This review article was undertaken to evaluate the role of laparoscopic fundoplication in the management of GERD and to find out answers to these controversial questions.

Key words: *Gastro-esophageal reflux disease (GERD); proton pump inhibitors (PPI); laparoscopic nissen fundoplication (LNF); short gastric vessels (SGV)*

Introduction

Gastro-esophageal reflux disease (GERD) is a very common medical disease. Normal competence of GE junction is maintained by lower esophageal sphincter (LES), which is influenced by its anatomical location in relation to diaphragm and its physiological function. The classic triad of symptoms of GERD is retrosternal burning pain (heartburn), epigastric pain and regurgitation. It is the most common condition affecting the upper GIT in western world. This is partly due to decreased incidence of peptic ulcers along with rising incidence of GERD in last 2-3 decades; incidence of peptic ulcer has decreased due to improved socioeconomic conditions leading to better control of H pylori infection. The strong association between GERD, obesity and the parallel rise in incidence of adenocarcinoma of lower third of esophagus is a major health concern today [1].

There is no consensus for optimal management of GERD. Proton pump inhibitors (PPI) are the most effective drug treatment for GERD. The number of antireflux procedures is on the rise, partly due to increased patient's expectations and partly due to the advancements in minimal access surgery.

Few pertinent questions need to be answered regarding optimal management of GERD.

1. Which modality is better; medical or surgical?
2. Is laparoscopic fundoplication superior to open approach?
3. Has Laparoscopic anterior fundoplication any advantages over Laparoscopic posterior fundoplication?
4. Does division of short gastric vessels during laparoscopic fundoplication offer any improvement in clinical outcomes?

This review article was undertaken to evaluate the role of laparoscopic fundoplication in the management of GERD and to find out answers to these controversial questions.

Review of literature

Literature search was performed to answer these questions. Online search engines like PubMed, Google, springer link library and Cochrane database systematic review were utilized and review articles, prospective and retrospective studies, which detailed or compared the various treatment strategies for GERD were selected and analyzed.

I. Medical treatment versus surgical treatment

Lundell L et al. published in 2001 their results of a randomized clinical study comparing antireflux surgery and

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omeprazole in GERD. There were 310 patients with erosive esophagitis enrolled in the study (155 in each group). At five-year follow-up, they found antireflux surgery to be more effective than omeprazole in controlling GERD, as measured by the treatment failure rate. But, if the dose of omeprazole was adjusted in case of relapse, levels of efficacy for two strategies were not significantly different [2].

Fernando HC published a retrospective study in 2002 regarding quality of life after surgery compared with medical treatment for GERD. Laparoscopic fundoplication was performed in 120 patients, whereas the medical cohort included 51 patients. They found that heartburn scores and QoL scores were superior after surgery, compared with medical therapy [3].

Papasavas PK et al. published a study in 2003 regarding effectiveness of laparoscopic fundoplication in eliminating antireflux medical therapy. They included 297 patients, who underwent laparoscopic fundoplication (Toupet, n=45; Nissen, n=252) and followed them for an average of 31.4 months. They found that only 10% of patients were on PPI at two years after surgery for typical GERD symptoms. They concluded that laparoscopic fundoplication offers a significant reduction in the need for chronic GERD medical treatment [4].

Results of seven years of follow-up of two groups were published in 2007. There were 119 patients in the omeprazole arm and 99 patients in antireflux surgery arm for evaluation. They found surgery to be more effective in controlling disease symptoms (66.7% versus 46.7% respectively, p=0.002) [5].

Cochrane database systemic review was published in 2010 to compare the effects of surgery versus medical treatment on health related and GERD specific QoL in patients with GERD. Four trials with a total of 1232 participants were included. There was a statistically significant improvement in health related QoL at 3 months and one year after surgery, compared to medical management. All four studies reported significant improvement in GERD specific QoL after surgery compared to medical therapy [6].

Galmiche JP published a RCT in 2011 comparing laparoscopic anti-reflux surgery with esomeprazole treatment for chronic GERD. The prevalence and severity of symptoms at five years in the esomeprazole and surgery group respectively, were 16% and 8% for heartburn (p=0.14), 5% and 11% for dysphagia (p<0.001), 13% and 2% for acid regurgitation (p<0.001), 28% and 40% for bloating (p<0.001) and 40% and 57% for flatulence (p<0.001). This multicenter clinical trial demonstrated that most of the patients achieve and remain in remission at five years in both groups (92% in esomeprazole group; 85% in surgery group) [7].

Thijssen AS et al (2011) did a systemic review regarding the cost effectiveness of PPI versus laparoscopic fundoplication. They included four publications, all of which were based on decision analytic models. The results with regard to cost effectiveness were inconclusive. All four economic models were based on high and low quality data [8].

Faria R (2013) published a REFLUX trial regarding cost effectiveness of laparoscopic fundoplication versus medical treatment for GERD. They concluded that laparoscopic fundoplication is a cost effective alternative to continued medical management [9].

Grant AM et al (2013) did clinical and economic evaluation of laparoscopic surgery compared with medical management for GERD in their five-year follow-up of multi center randomized trial (the REFLUX trial). They concluded that at five years, laparoscopic fundoplication continues to provide better relief of GERD symptoms with associated improvement in health related QoL [10].

Rickenbacher N et al published a systematic review and meta-analysis in 2014 comparing medical and surgical treatments (open and laparoscopic) of GERD. The study included eleven publications reporting on seven trials comparing the two modalities. They found that surgical treatment is more effective than medical management with respect to patient-relevant outcomes. Heartburn and regurgitation were less frequent in the surgery group with higher patient satisfaction [11].

A Cochrane database systematic review was done in 2015. A total of 1160 participants in the four RCT's were randomly assigned to laparoscopic fundoplication (n=589) or medical treatment with PPI (n=571). None of the trials reported long term health related quality of life (HRQoL) or GERD specific quality of life (QoL). The difference between laparoscopic fundoplication and medical treatment was imprecise for overall short term HRQoL, medium term HRQoL, medium term GERD specific QoL, proportion of people with adverse events, long term dysphagia and long term reflux symptoms. The short term GERD specific QoL was better in the laparoscopic group than in the medical treatment group. The proportion of people with serious adverse events, short term and medium term dysphagia was higher in the laparoscopic fundoplication group. The proportion of people with heartburn (at short, medium and long term) and those with reflux symptoms (at short term and medium term) was lower in the laparoscopic fundoplication group than in the medical treatment group. They concluded that, there is considerable uncertainty in the balance of benefits versus harms of surgery, compared to long term medical treatment [12].

II. Laparoscopic versus conventional open fundoplication

Frantzides CT (1995) compared operative and short term results of open fundoplication (n=29) with Laparoscopic

procedure (n=36). Operative time was comparable in both the groups (2.8±0.4 hrs versus 3.1±0.3 hrs). Hospital stay was significantly less in laparoscopic group (9.2±0.7 days versus 1.8±0.2 days). There was no difference in resolution of symptoms in both groups [13].

Watson DI reviewed literature in 2004 and concluded that laparoscopic approach is superior to medical therapy for the treatment of GERD. He also demonstrated that laparoscopic approach achieves an improved short term outcome, compared to open technique. He labeled Laparoscopic fundoplication as the 'Gold Standard' for treatment of patients with more severe GERD [14].

Franzen T et al (2005) did a prospective randomized clinical trial between laparoscopic (n=45) and open (n=48) 360 degree fundoplication. Early post-operative reflux control was similar in both the groups but in long term follow-up, significantly more patients were satisfied in open group (91%) than laparoscopic group (62%) [15].

Hakanson BS et al (2007) carried out a prospective randomized trial comparing open (n=93) and laparoscopic (n=99) partial posterior fundoplication. Reflux control and patient-assessed satisfactory outcome at 3-year follow-up were similar in both groups. They concluded that, fewer general complications, shorter hospital stay, fast recovery and comparable three-year outcome make laparoscopic approach the primary choice [16].

Peters MJ et al (2009) published a meta-analysis of Randomized clinical trials comparing open and laparoscopic antireflux surgery. A total of 12 trials were considered suitable. There were 503 patients in open group and 533 in laparoscopic group. Laparoscopic group showed shorter hospital stay, low peri-operative complications and early return to normal activities with comparable treatment failure rates. The operative time and requirement for further surgery was significantly higher in laparoscopic group [17].

Salminen P (2009) reviewed literature to highlight the long term results of Laparoscopic Nissen fundoplication. He concluded that laparoscopic approach has a similar long term symptomatic outcome as the open one but with a significantly low incidence of incisional hernia and defective fundic wraps [18].

Broeders JA et al (2009) compared a ten-year outcome of a multicentric randomized controlled trial on laparoscopic and conventional Nissen fundoplication. A total of 148 patients (79 in laparoscopic group, 69 in open group) were involved in this study. The ten-year effectiveness of both procedures was similar in terms of improvement of GERD symptoms, but open approach carries a higher risk for surgical reintervention, compared with laparoscopic approach, mainly due to development of incisional hernias [19].

McHoney M et al (2011) carried out a RCT of Laparoscopic versus open Nissen fundoplication in infants and children. Twenty open cases and nineteen laparoscopic cases were included. There was no difference in analgesic requirements, hospital stay, dysphagia, recurrence and need for redo fundoplication. However, retching was higher after open surgery (56% versus 6%; p=0.003) [20].

Salminen P et al (2012) carried out a study to compare the fifteen-year outcome of a randomized controlled study of laparoscopic versus open Nissen fundoplication. There were 48 patients in the laparoscopy group and 38 patients in the open surgery group. Long term symptomatic outcome was similar in both the groups but significantly greater number of disrupted complications (p=0.0115) and incisional hernias (p <0.001) occurred in open fundoplication group [21].

Qu H et al (2014) did a systematic review and meta -analysis of randomized controlled trials. They included 12 trials (N=1067) with 557 patients in Laparoscopic group and 510 patients in open fundoplication group. Laparoscopic group showed higher operative time but decreased hospital stay and complication rates. Reflux symptoms were more frequent in Laparoscopic group in short term follow-up but in long term, Laparoscopic group patients showed better control of reflux symptoms (p<0.05) [22].

III. Nissen versus Toupet versus Dorr

Although Laparoscopic posterior fundoplication (LPF) i.e Nissen (Total 360 degree) or Toupet (partial 270 degree) have the proven efficacy for the management of GERD, postoperative dysphagia and gas bloat syndrome is a significant problem associated with them. Laparoscopic anterior fundoplication (LAF, Dorr), partial 180 degree, was introduced to decrease some of these complications.

Khan M et al (2010) did a RCT of LAF versus LPF for GERD. The mean operating time was similar in both groups (48 versus 52 min). Post-operative dysphagia was higher in the posterior fundoplication group, compared with the anterior group (at 1 month, P= 0.002; and at 3 months, P= 0.014). The number of individuals suffering from post-operative heartburn was greater in the LAF group (at one month, P= 0.008; at three months, P <0.001; and at six months, P= 0.002) [23].

Chen Z et al (2011) published a 16-year experience of anterior 180 degree partial fundoplication (n=548). They concluded that, Laparoscopic anterior 180-degree partial fundoplication is an effective and durable alternative to Nissen fundoplication for the surgical treatment of gastroesophageal reflux [24].

Broeders JA et al (2011) did a systematic review and meta-analysis of RCT's comparing laparoscopic anterior and posterior fundoplication. Eleven reports on 7 eligible RCTs (anterior vs. posterior total [n=5]; anterior vs. posterior partial [n=2]) comparing LAF (n=345) versus LPF (n=338) were included. Short-term (6-12 months) esophageal acid

exposure time (3.3% vs. 0.8%; P <0.001), heartburn (21% vs. 8%; P <0.001) and reoperation rate (8% vs. 4%; P = 0.06) were higher after LAF. In the short-term this was counterbalanced by less severe dysphagia. However, dysphagia scores became similar in the long-term. Authors labeled it as "level 1a support" for the use of LPF as the surgical treatment of choice for GERD [25].

Cao Z et al (2012) published 5-year results of a randomized clinical trial, comparing laparoscopic anterior 180 degree partial versus 360 degree Nissen fundoplication. They concluded that anterior 180 partial fundoplication is an effective treatment of gastroesophageal reflux and is associated with fewer postoperative ad verse effects [26].

Broeders JA et al (2012) reviewed four randomized trials, comparing anterior partial versus Nissen fundoplication. Two trials evaluated anterior 180 and 2 anterior 90 partial fundoplication (Total n=461). They concluded that anterior 180 partial fundoplication achieves durable control of reflux symptoms and fewer side effects compared with Nissen fundoplication at 5-year follow-up; reflux control after anterior 90 partial fundoplication appears less effective [27].

Ma S et al (2012) did a meta-analysis comparing Toupet versus Nissen. Thirteen randomized trials were considered suitable for the meta-analysis. A total of 1374 patients underwent Toupet or Nissen. There was a significant reduction of the incidence of post-operative dysphagia (OR = 0.44, P <0.0001) and inability to belch (OR = 0.41, P <0.005) for the Toupet compared to that of the Nissen group. Compared with Toupet, Laparoscopic Nissen resulted in a significant reduction of the incidence of post-operative heartburn (OR = 1.94, P <0.01).They concluded that both Toupet and Nissen are effective for the treatment of proven gastro-oesophageal reflux disease. Toupet enables a decreased post-operative dysphagia and gas-related side effects, while Nissen is more successful in controlling reflux symptoms, particularly heartburn [28].

Mauritz FA et al (2013) did a systematic review and meta-analysis of complete versus partial fundoplication in children with GERD. Eight original trials comparing complete to partial fundoplication were included. Seven of these studies had a retrospective study design. This systematic review and meta-analysis showed that reflux control is similar after both complete and partial fundoplication, while partial fundoplication significantly reduces the number.

Daud WN et al (2015) did a randomized controlled trial comparing Laparoscopic Toupet with laparoscopic Dorr. Forty-seven patients were randomized to Dorr (n = 23) versus Toupet (n=24) fundoplication. At twelve months, the mean heartburn score was higher when following Dorr (2.7 versus 0.8, P = 0.045), although differences were not significant at earlier follow-up. Conversely, following Toupet fundoplication, patients were less able to belch at three (56% versus 16%, P = 0.013) and six months (43% versus 9%, P = 0.017). Authors concluded that Toupet is associated with less reflux symptoms, but more side effects [30].

Memon MA et al (2015) did a meta-analysis and systematic review of RCT's, comparing LAF with LPF. They included nine trials with a total of 840 patients (LAF=425, LPF=415). There was a significant reduction in odds ratio for dysphagia in the LAF group and for heartburn in the LPF group. The two groups were similar regarding other variables, like operative time, overall complications, conversion rates, length of hospital stay, patient's satisfaction, redo surgery and post-operative 24 hours pH scores. They concluded that LPF is a better alternative to LAF for controlling GERD symptoms due to better control of heartburn; though at the expense of higher dysphagia [31].

IV. Short gastric vessels (SGV) Division

It has been claimed that dividing the SGV during laparoscopic Nissen fundoplication increases the risk of troublesome side effects, such as dysphagia, inability to belch and abdominal bloating; so many centers have started doing laparoscopic Nissen without division of SGV (Rossetti modification).

Watson DI et al (1997) carried out a prospective double blind randomized trial in which laparoscopic Nissen fundoplication was done in 52 patients with division of SGV and in 50 patients without division. They concluded that operative time gets prolonged by 40 minutes (median 105 versus 65 mins) by vessel division without any improvement in clinical or objective post-operative outcome [32].

Chrysos E et al (2001) did a prospective randomized trial comparing nissen (n=24) to nissen-Rossetti technique (n=32). They concluded that division of SGV is associated with increased operative time (p <0.0001) and increased incidence of 'gas-bloat' syndrome with no improvement in clinical outcome [33].

A prospective double blind randomized trial with 5-year follow-up was done by O' Boyle CJ et al (2002). A total of 99 patients (SGV intact in 50, divided in 49) were interviewed telephonically at 5-year follow-up. It was seen that division of SGV does not improve any clinical outcome and is associated with increased incidence of 'wind related' problems like flatus production and epigastric bloating [34].

Yang H et al (2008) published 10year outcomes of a randomized trial. There were total 102 patients (SGV divided in 50, SGV left intact in 52). At 10-year follow-up, heartburn, dysphagia and overall satisfaction were similar in both groups [35].

Kosek V et al (2009) observed a clinical and functional outcome of division of SGV during laparoscopic Nissen, during the long term follow up in a prospective randomized trial. 19 patients (group 1) underwent fundoplication with-

out division of SGV and 22 patients (group 2) with division of SGV. There was significant difference in mean operative time (109 versus 125 minutes, p<0.05) and mean blood loss (p <0.05). Authors concluded that routine division of SGV during nissen yields neither functional nor clinical advantages in short or long term follow up [36].

Mardani J et al (2009) published 10-year results of a randomized clinical trial of laparoscopic total fundoplication with or without division`n of SGV (57 versus 47). They found that both types of repair provide adequate reflux control [37].

Ielpo B et al (2011) published a retrospective case note review study of patients undergoing LNF with division of SGV (n=64) or without division (n=59). Mean operative time was significantly lower in intact SGV group (90 versus 115 minutes, p<0.04). There was no difference in DeMeester score, lower esophageal sphincter resting pressure and long term satisfaction score between the two groups at 36-60 months follow-up [38].

Engstrom C et al (2011) did a meta-analysis of two RCT's to identify long-term symptoms after SGV division during Nissen fundoplication. 99 OG patients enrolled in the Swedish study and 102 in the Australian study, the SGV were divided in 104 patients and left intact in 97. There was no significant difference in symptoms of heartburn, dysphagia and ability to belch. Division of SGV was associated with higher rates of bloating symptoms (p=0.002). They concluded that surgeons should avoid dividing these vessels during laparoscopic nissen fundoplication [39].

Markar SR et al did a systematic review and meta-analysis in 2011. They included 5 RCT's. There was no statistically significant difference in length of hospital stay, post-operative complications, post-operative gas bloat syndrome, DeMeester score, requirement for re-operation and post-operative dysphagia or reflux. SGV division was associated with a longer operative time and reduced lower esophageal sphincter pressure post-operatively [40].

A meta-analysis was carried out by Khatri K et al (2012). They included 5 RCT's (total 388 patients). Both groups were having 194 patients each. SGV division was associated with longer operative time and hospital stay. There was no difference in terms of functional outcome at 1-year and 10-year follow-up [41].

Conclusion

Both medical and surgical modalities are effective means of controlling GERD. Laparoscopic fundoplication seems to be more effective in controlling disease symptoms, especially heartburn and regurgitation, but has its own disadvantages being a surgical procedure. There is a need of trial reporting long term health related quality of life, or GERD specific quality of life to remove uncertainty in the balance of benefits versus harms of surgery, compared to long term medical therapy.

Laparoscopic surgery has an edge over open surgery, due to shorter hospital stay, early return to normal activities, and comparable long term treatment outcome with a significantly low incidence of incisional hernia.

Among different types of wrap, Nissen's complete fundoplication is more successful in controlling reflux symptoms particularly heartburn; these advantages are often counter-balanced by increased post-operative dysphagia and gas related side effects. Anterior wraps and partial wraps are associated with decreased incidence of dysphagia.

Division of short gastric vessels during laparoscopic Nissen fundoplication increases operative time and 'wind related' complications with no functional or clinical advantages in short or long term follow-up. We may conclude that routine division of SGV during laparoscopic Nissen fundoplication should be avoided.

Conflict of Interest: *The authors declare that there is no conflict of interest.*

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