

META-ANALYSIS OF LAPAROSCOPIC POSTERIOR AND ANTERIOR FUNDOPPLICATION FOR GASTRO-OESOPHAGEAL REFLUX DISEASE

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ABSTRACT

Objectives: Although laparoscopic posterior (Nissen) fundoplication (LPF) has the proven efficacy for controlling gastro-oesophageal reflux surgically, there remain problems with postoperative dysphagia and the inability to belch or vomit. To decrease some of these postoperative complications, laparoscopic anterior fundoplication (LAF) was introduced. The aim of this study was to conduct a meta-analysis of RCTs to investigate the merits of LPF vs LAF for the treatment of gastro-oesophageal reflux disease (GORD).

Data Sources and Review Methods: A search of Medline, Embase, Science Citation Index, Current Contents, PubMed and the Cochrane Database identified all RCTs comparing different types of laparoscopic posterior and anterior fundoplications published in the English Language between 1990 and 2008. The eight variables analysed included operative time, overall complications, rate of conversion to open, re-do operative rate, dysphagia score, heartburn rate, visick grading of satisfaction and overall satisfaction.

Results: Five trials totalling 556 patients (Posterior=277, Anterior=279) were analysed. The analysis showed trends favouring LPF in terms of overall complication rate, conversion rate, incidence of postoperative heartburn and re-do operative rate. There was significant improvement in the postoperative satisfaction score in terms of reflux symptoms favouring LPF while there was significant reduction in the dysphagia score favouring LAF. No difference was noted in operating time and Visick's grading of satisfaction between the two groups.

Conclusions: Based on this meta analysis, LPF is associated with fewer complications, decreased rate of conversion, heartburn rate, re-operation rate and significantly higher overall satisfaction rate for controlling GORD symptoms. However the LAF was associated with a significantly lower incidence of dysphagia compared to its posterior counterpart. We therefore conclude that LPF is a better alternative to AFP at the expense of higher dysphagia rate.

Keywords: Fundoplication; Anti-reflux; Posterior fundoplication; Nissen fundoplication; Anterior antireflux surgery; Gastro-oesophagael reflux disease; Randomised controlled trials

1. INTRODUCTION

The "Open Nissen Fundoplication", and its modifications have been employed to treat moderate to severe gastro-oesophageal reflux disease (GORD) for almost six decade now. The procedure involves 360° posterior wrapping of the fundus of the stomach around the distal oesophagus. Laparoscopic fundoplication, the minimally access modification of the original Nissen fundoplication was first described by Dallemagne in 1991 (Dallemagne et al., 1991) following the success of laparoscopic cholecystectomy. Although this type of fundoplication achieves good control of GORD, some patient may experience troublesome postoperative side effects such as dysphagia, an inability to vomit or belch (gas bloat syndrome) and excessive flatulence. To alleviate this problem partial posterior and anterior fundoplications were introduced where the wrap extended from 90° to 270° either posteriorly or anteriorly. The question of which technique offers the best results in terms of control of GORD with minimal side effects remains controversial. Many uncontrolled single centre series claim good results with partial posterior (Bell, 1996, O'Reilly, 1996) or anterior fundoplication (Watson et al., 1991, 1995, Rice et al., 2006). However, there have been few RCTs undertaken to address this controversial issue in an evidence based manner (Hagedorn et al., 2003, Watson et al., 1999, 2004, Baigrie et al., 2005, Spence et al., 2006). The problem is further compounded by the fact that only a few of these RCTs have long term follow-up.

The aim of this meta-analysis was to investigate the benefits and risks of LAP versus LPF for the treatment of GORD. Five randomised controlled trials (Hagedorn et al., 2003, Watson et al., 1999, 2004, Baigrie et al., 2005, Spence et al., 2006) comparing these procedures have been published over the last seven years. This meta-analysis considers pooled data from all of the available randomised clinical trials that compared LAF and LPF methods of anti-reflux surgery, and was prepared in accordance with the Quality of Reporting of Meta-analyses (QUOROM) statement (Moher et al., 1999).

2. MATERIAL AND METHODS

All randomised clinical trials of any size that compared any type of LAF with LPF for the treatment of GORD, and were published in full in peer-reviewed journals in the English language between January 1990 and the end of May 2008 were included (Table 1). Studies must also have reported on at least one clinically relevant outcome. Unpublished studies and abstracts

presented at national and international meetings were excluded. Eight outcome variables which were considered most suitable for analysis included:

1. Operative time
2. Overall complications
3. Rate of conversion to open
4. Re-do operative rate
5. Dysphagia score
6. Heartburn rate
7. Visick grading of satisfaction
8. Overall satisfaction

Trials were identified by conducting a comprehensive search of Medline, Embase, Science Citation Index, Current Contents and Pubmed databases, using medical subject headings “fundoplication”, “anti-reflux”, “posterior fundoplication”, “Nissen fundoplication”, “anterior antireflux surgery”, “gastro-oesophagael reflux disease”, “comparative studies”, “prospective studies”, “randomised controlled trials”, “random allocation” and “clinical trial”. Manual search of the bibliographies of relevant papers was also carried out to identify trials for possible inclusion.

Data extraction and critical appraisal were carried out by three authors (MSS, BM and MAM) for compliance with inclusion criteria and methodological quality. Standardised data extraction forms (Moher et al., 1999) were used by authors to independently and blindly summarise all the data available in the RCTs meeting the inclusion criteria. The authors were not blinded to the source of the document or authorship for the purpose of data extraction. The data were compared and discrepancies were addressed with discussion until consensus was achieved.

Evaluation of the methodological quality of identified studies was conducted using the Jadad scoring system (Jadad et al., 1996) in which each study was assigned a score of between zero (lowest quality) and 5 (highest quality) based on reporting of randomization, blinding, and withdrawals occurring within the study (Table 2).

3. STATISTICAL ANALYSIS

Meta-analyses were performed using odds ratios (ORs) and relative risk (RR) for binary outcomes and weighted mean differences (WMDs) for continuous outcome measures. A slightly amended estimator of OR was used to avoid the computation of reciprocal of zeros among observed values in the calculation of the original OR (Liu et al., 1996). Random effects models, developed by using the inverse variance weighted method approach were used to combine the data (Sutton et al., 2000). Heterogeneity among studies was assessed using the Q statistic proposed by Cochran (Sutton et al., 2000, Hedges et al., 1985) and I^2 index introduced by Higgins and Thompson (Higgins et al., 2002, Huedo-Medina et al., 2006). If the observed value of Q is larger than the critical value at a given significant level, in this case 0.05, we conclude that the outcome variable is statistically significant. For the computations of the confidence intervals estimates of mean and standard deviation are required. However, some of the published clinical trials did not report the mean and standard deviation, but rather reported the size of the trial, the median and range. From these available statistics, estimates of the mean and standard deviation were obtained using formulas proposed by Hozo (Hozo et al., 2005). Funnel plots were synthesized in order to determine the presence of publication bias in the meta-analysis. Both total sample size and precision ($1/\text{standard error}$) were plotted against the treatment effects (OR for the dichotomous variables: complications, conversion rate, dysphagia, heartburn and reoperation (Sutton et al., 2000, Egger et al., 1997,). All estimates were obtained using computer programs

written in R (R: A language and environment for statistical computing [computer program]. Version 2.8.0. Vienna: Foundation for Statistical computing; 2008). All plots were obtained using the 'rmeta' package (Lumley T. The rmeta Package Version 2.14).

In the case of tests of hypotheses, the paper reports *p*-values for different study variables. In general, the effect is considered to be statistically significant if the *p*-value is small. If one uses a 5% significance level then the effect is significant only if the associated *p*-value is less than or equal to 5%.

4. RESULTS

There was almost a perfect agreement ($\kappa=0.99$) between the three authors (MSS, BM, MAM) regarding the inclusion and exclusion of various randomized controlled trials. Based on this agreement, a total of five randomized prospective clinical trials (Hagedorn et al., 2003, Watson et al., 1999, 2004, Baigrie et al., 2005, Spence et al., 2006) involving a total of 556 patients (LAF=279, LPF=277) were considered suitable for meta-analysis. None of the five trials achieved a modified Jadad score of more than 2 (Table 1).

A statistically significant reduction of 4.9 in WMD for the dysphagia score was noted favouring LAF (WMD 4.8982, CI 2.4753, 7.3211, $p<0.0001$). On the other hand, there was a significant 59% reduction in the relative odds of heartburn seen in patients receiving LPF (OR 0.4145, CI 0.1785, 0.9625, $p=0.0405$). Comparable effects were seen for LPF and LAP for other variables which include operating time (WMD 1.5581, CI -4.8591; 7.9753, $p=0.6342$), overall complications (OR 0.4547, CI 0.1874, 1.1035, $p=0.0815$), conversion rate (OR 0.899, CI 0.2279, 3.5465, $p=0.8791$), Visick grading (OR 1.41, CI 0.67, 2.95, $p=0.3631$), patient's satisfaction (WMD -0.1848, CI -0.6002; 0.2305, $p=0.383$) and redo surgery (OR 0.6538, CI 0.2889, 1.4799, $p=0.308$) (Table 2).

5. DISCUSSION

It is well documented that while LPF is associated with higher rates of dysphagia, the LAF is accompanied by worse reflux control (Hagedorn et al., 2003). This is supported objectively by the findings of Anderson (Anderson et al., 1998) in his RCT where Nissen (LPF) fundoplication was found to have a greater elevation of resting (33.5 vs. 23 mm Hg) and residual lower esophageal sphincter pressures (17 vs. 6.5 mm Hg) and lower esophageal ramp pressure (26 vs. 20.5 mm Hg) than the LAF. A smaller radiologically measured sphincter opening diameter was seen following Nissen fundoplication (9 mm) compared with anterior fundoplication (12 mm).

Various modifications have been tried to better the outcome in relation to reflux control and dysphagia, such as varying the degree of wrap and division of short gastric vessels. Division of short gastric vessels have failed to show any improvement in the overall outcome with regards to postoperative symptoms such as dysphagia in either laparoscopic or open fundoplication (Watson et al., 1997, 1999, Blomqvist et al., 2000, Luostarinen and Isolauri, 1999). This fact is further proven by Engstrom (Engstrom et al., 2004) in her RCT which involves 24 patients undergoing Laparoscopic Nissen Fundoplication divided into 2 groups, with and without short gastric divisions, where there was no difference in the rate of dysphagia or reflux control achieved.

There remains controversy regarding the correlation between division of short gastric vessels and wind related problems mainly belching and bloating. While Luostarinen (Luostarinen and Isolauri, 1999) showed no change in wind related problems with division of the short gastrics, Boyle (O'Boyle et al., 2002) and Chrysos (Chrysos et al., 2001) showed increased bloating and flatus with division of the short gastrics. Luostarinen's RCT involved 50 patients who underwent

Nissen Fundoplication, with and without short gastrics division and at 5 years showed no difference in wind related problems with either group. Boyle's RCT involved 102 patients undergoing Nissen fundoplication and at 3 years showed, in the group having division of the short gastrics, an increased incidence of epigastric bloating (71% vs. 48%) and increased flatus (88% vs. 70%) compared to the group without the division of short gastric. Chrysos in his RCT involving 56 patients undergoing Nissen fundoplication, at 1 year showed an increased incidence of bloating in the group who had division of the short gastric (38%) compared to the group without short gastric division (19%).

Trials involving partial posterior fundoplication which were conducted in an attempt to eliminate certain postoperative problems such as dysphagia and bloating associated with total wrap posterior fundoplication managed to eliminate bloating but failed to decrease the rate of dysphagia. A ten year follow up result of a RCT involving 137 patients comparing laparoscopic Toupet (180 degree posterior) and Nissen fundoplication reported by Hagedorn (Hagedorn et al., 2002), showed no difference in the rate of dysphagia (41% vs. 38%) but significantly less bloating (54% vs. 66%, $p < 0.03$) and flatulence (72% vs. 90%, $p < 0.001$). Walker et al. (1992) in his RCT involving 52 patients compared Lind (300 degree posterior) and Nissen fundoplication where he found no difference in the rate of postoperative dysphagia but a significant improvement in bloating in patients undergoing Lind fundoplication ($p < 0.05$)

Partial posterior fundoplication on the other hand has better reflux control than the partial anterior fundoplication as shown by the long term results of the Swedish trial (Hagedorn et al., 2003), the only RCT to compare 2 partial fundoplications (Posterior 180 vs. anterior 120). The 5 year follow up result of this trial reported by Engstrom (Engstrom et al., 2007) showed that 82.2% has no reflux symptoms in the LPF group in comparison to only 34.9% in the LAF group. It had similar figures with respect to the patient being able to belch (86.7% in LPF, 88.4% in LAF) but had much worse results with ability to vomit (27.3% in LPF, 63.4% in LAF).

Ludemann (Ludemann et al., 2005), in his 5 year follow up report of an RCT involving 105 patients, initially conducted by Watson (Watson et al., 1999) concluded that anterior fundoplication (180 degree) has a reflux control as good as Nissen fundoplication. Both at the end of 5 years had 90% of patients with good reflux control and not on any PPIs.

Hagedorn (Hagedorn et al., 2003) on the other hand in his RCT involving 96 patients comparing 120 degree anterior and Nissen fundoplication reports a worse reflux control with the former procedure (34% vs. 73%). Similarly Watson (Watson et al., 2004) in his RCT involving 112 patients comparing 90 degree anterior with Nissen fundoplication reports a worse reflux control with the anterior fundoplication (79% vs. 95%). A single centre prospective trial by Rice (Rice et al., 2006) involving 117 patients who underwent 180 degree anterior fundoplication revealed that at 5 years (99% of patients were available for follow up) 80% of patients have a full reflux control and not needing any PPIs. Furthermore 95% of the patients were highly satisfied overall. These results were based on patient questionnaires and not on any manometric or endoscopic follow up.

Very few studies have published long term outcomes for laparoscopic fundoplication. A number of authors have shown previously better outcomes with short term follow up which are not matched by long term follow up results (Ludemann et al., 2003). Kneist et al. (2003) showed in a retrospective study a significant improvement of heartburn with anterior fundoplication after 44 months of follow up, where as Engstrom (Engstrom et al., 2007) in a RCT comparing anterior and posterior fundoplication found that posterior fundoplication yielded better control of reflux after 65 months of follow up. In the RCT by Watson (Watson et al., 1999), at 5 years there was a higher number of patients with heartburn in the anterior fundoplication group, easily controlled with PPIs, however the posterior fundoplication group had a higher number of patients with dysphagia, although patients in both groups were more satisfied overall postoperatively

(Ludemann et al., 2005). At 10 years both groups of patients had a good results in terms of heartburn, but anterior fundoplication group had decreased incidence of dysphagia (Cai et al., 2008). A 10 year retrospective study from Fein (2008) involving 120 patients also showed that regurgitation persisted in only 15% of the patients in the Nissen group compared to 44% in the anterior fundoplication group.

Finally, surgeons experience has to be taken into account when determining the long term outcome of reflux control. A 5 year follow up of a prospective trial comparing open and laparoscopic Nissen with anterior fundoplication showed no difference in the control of reflux symptoms (Stewart et al., 2004). A 5 year follow up of a prospective study of laparoscopic fundoplication involving 2 groups, during the learning curve and thereafter, shows a significant improvement in the re-operation rate for persisting reflux from 15% to only 6% (Jamieson, 2005). Therefore surgeons experience has a significant role to play especially if the trial is conducted during the learning curve of the surgeons involved.

6. CONCLUSIONS

Based on this meta-analysis, LPF is associated with fewer complications, decreased rate of conversion, heartburn and re-operation, and significantly higher overall satisfaction among patients. However the LAF was associated with a significantly lower incidence of dysphagia. We therefore conclude that LPF is a better alternative to LAF at the expense of a higher dysphagia rate.

APPENDIX

Table 1: Details of all the RCTs

Authors	Year/Country	No of Patients		Types of Fundoplications	Division of Short Gastrics	Jadad Score
		LAF	LPF			
Watson et al	1999/Australia	54	53	Anterior 180 vs Nissen 360	No	2
Hagedorn et al	2003/Sweden	47	48	Anterior 120 vs Posterior 180	Yes	2
Watson et al	2004/Australia	60	52	Anterior 90 vs Nissen 360	Yes	2
Baigrie et al	2005/South Africa	79	84	Anterior 180 vs Nissen 360	No	2
Spence et al	2006/Australia	39	40	Anterior 90 vs Nissen 360	No	2

Table2: Summary of pooled data comparing posterior and anterior fundoplication

Outcome Variables	Patients n	Pooled OR WMD (95% CI)	Test for overall effect		Test for heterogeneity		
			Z	p value	Q	p value	I ² index
Operation time	512	1.5581 (-4.8591; 7.9753)	0.4759	0.6342	33.83	0.0001	91.1%
Overall complications	298	0.4547 (0.1874; 1.1035)	-1.7422	0.0815	1.78	0.411	0%
Conversion rate	461	0.899 (0.2279; 3.5465)	-0.1521	0.8791	2.31	0.5099	0%
Dysphagia	393	4.8982 (2.4753; 7.3211)	3.9623	< 0.0001	223.94	0.0001	98.7%
Heartburn	393	0.4145 (0.1785; 0.9625)	-2.0488	0.0405	5.71	0.1266	47.5%
Visick grading	462	1.41 (0.67; 2.95)	0.9095	0.3631	0.23	0.9719	0%
Satisfaction	461	-0.1848 (-0.6002; 0.2305)	-0.8723	0.383	1.65.47	0.0001	98.2%
Redo surgery	461	0.6538 (0.2889; 1.4799)	-1.0194	0.308	0.36	0.948	0%

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