Laparoscopic Nissen fundoplication versus 90° and 180° fundoplication for gastroesophageal reflux disease

Systematic review and meta-analysis of 5-year outcomes

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Summary

Background Laparoscopic Nissen fundoplication (LNF) is standard care for surgical treatment of gastroesophageal reflux disease (GERD) in adults. The main disadvantage is the compression of the food passageway, affecting the ability to belch and vomit, and causing swallowing difficulties. Therefore, partial fundoplication methods encircling esophagus as little as 90° and 180° have been developed. Previous studies have been inconclusive. The aim was to assess the effectiveness of LNF compared to laparoscopic anterior 90° and 180° fundoplication.

Methods Randomized controlled trials were searched for in MEDLINE, Embase, CINAHL, the Cochrane Library, and Web of Science, and in eligible studies’ reference lists and relevant reviews. Outcomes of interest were 5-year heartburn, medication use, dysphagia, reoperation, and satisfaction. Dichotomous data were calculated as risk ratios (RR). Subgroup analyses were performed to compare each comparator separately with LNF. The meta-analyses were conducted using a random-effects model with an inverse variance statistical method and a significance level of 0.05.

Results Four eligible trials were included with 398 participants, of which half compared LNF with 90°. At 5 years there was higher risk of dysphagia for solids after LNF compared to 90° and 180° fundoplication (RR 1.68 [1.14, 2.49]). However, LNF was associated with a significantly lower risk of medication use compared to laparoscopic anterior 90° fundoplication (RR 0.23 [0.09, 0.58], subgroup analysis). No differences between treatments in terms of heartburn, reoperation, and satisfaction were found.

Conclusion The limited evidence fails to provide an unequivocal method of choice, but rather indicates a trade-off between reflux control and complications.

Keywords Heartburn · Proton pump inhibitors · Dysphagia · Reoperation · Patient satisfaction

Main novel aspects

- This is the first systematic review and meta-analysis to specifically investigate both degrees (90° and 180°) in relation to laparoscopic Nissen fundoplication (LNF).
- This review studies a few key outcomes, whereas previous systematic reviews frequently included numerous outcomes. Therefore, the previous reviews include several statistical analyses for which a multiple comparisons problem is deemed possible.
- This review studies the outcomes at a definite long-term timepoint (5 years) to be able to know whether these options stand the test of time, but long-term follow-up at a specific timepoint has seldom been studied. Previous reviews have studied follow-ups from set timepoints to indefinite or indeterminate periods, which raises some doubt about the validity of assuming independent events.

Introduction

Gastroesophageal reflux disease (GERD), commonly with symptoms of heartburn and regurgitation, is...
A prevalent digestive disorder worldwide [1–3]. Productivity loss and decreased wellbeing are associated with GERD as well as the risk for other conditions such as esophagitis and Barrett’s esophagus [2, 3].

Several treatment options are available, of which pharmacotherapy, mainly proton pump inhibitors (PPIs), is commonly used [1, 4–7]. However, medication only acts to relieve symptoms, which will return if treatment is stopped [1, 4, 5]. Surgical treatments, on the other hand, aim to target the cause of the reflux [1, 4, 5]. Laparoscopic Nissen fundoplication (LNF), involving a complete 360° wrap using both anterior and posterior fundic walls, is one of the most used procedures and seen by some as the gold standard [4–6]. Alternative approaches commonly used include laparoscopic posterior 270° fundoplication (Toupet fundoplication), laparoscopic anterior 180° fundoplication, and laparoscopic anterior 90° fundoplication [4–6].

Treatment regimens for GERD have been extensively researched [4, 5, 8, 9], in particular LNF, given the numerous published systematic reviews and randomized controlled trials regarding the procedure [10–21]. Reviews have the ability to summarize evidence into knowledge [22]. However, previous reviews differ markedly in terms of the treatment methods being compared, follow-up, and outcome measurements [10–19].

LNF may cause dysphagia and has mainly been compared with Toupet, intended to reduce dysphagia, without a definite conclusion in the available reviews [14–18]. This calls for further comparisons with laparoscopic anterior 90° and 180° fundoplication, with the option to further reduce dysphagia [14–19]. Existing reviews have either compared all existing antireflux procedures [8, 9, 12] or only laparoscopic anterior 180° fundoplication [10, 19]. To our knowledge, only one study has investigated both degrees in relation to LNF; however, this was not a systematic review [20].

LNF and the shorter fundoplication methods (90° and 180°) have been studied in reviews at follow-ups ranging from set timepoints to indefinite or indeterminate periods [8–10, 12, 19]. This range raises some doubt about the validity of assuming independent events. Furthermore, long-term follow-up at a specific timepoint, such as 5 years after surgery, has seldom been studied. Being an invasive treatment option, it is important to study the long-term outcomes of surgical methods and see whether they stand the test of time.

Performance and safety as well as patient perception of a procedure are important aspects to study.
Table 1  Characteristics of the included studies

| Study          | Setting                  | Method                                      | Participants                  |
|----------------|--------------------------|---------------------------------------------|-------------------------------|
|                |                          |                                             | Sample size | Sex (n male) | Age (years, mean) |
| Cao et al. (2012) [25] | China                   | LNF, Laparoscopic anterior 180° fundoplication | 50           | 21           | 59.1              |
| Ludemann et al. (2005) [26] | Australia                | LNF, Laparoscopic anterior 180° fundoplication | 53            | NR           | NR                |
| Nijjar et al. (2010) [27] | Australia, New Zealand   | LNF, Laparoscopic anterior 90° fundoplication | 52            | 33           | 40                |
| Watson et al. (2012) [28] | Australia                | LNF, Laparoscopic anterior 90° fundoplication | 39            | 19           | 45.7              |

LNF: Laparoscopic Nissen fundoplication, NR: not reported

However, previous systematic reviews often included numerous outcomes and, therefore, several statistical analyses [8–10, 12, 19]. A multiple comparisons problem is therefore deemed possible.

Methodological choices and inconclusive results from previous research demonstrate the need for a systematic review and meta-analysis that seeks to answer the question about LNF’s effectiveness in relation to shorter fundoplication methods for GERD using a few key outcomes measured at a definitive long-term timepoint.

**Objective**

To assess the effect of LNF for adults with GERD compared to laparoscopic anterior 90° and 180° fundoplication with focus upon reflux control, complications, and satisfaction 5 years after surgery.

**Materials and methods**

This study adheres to the Cochrane handbook on systematic reviews 5.1.0 [22], with the preregistered protocol PROSPERO (2017 CRD42017075895).

**Eligibility criteria**

- Randomized clinical trial with at least one arm being LNF.
- Adults (≥18 years old) with clinically diagnosed GERD, irrespective of manifestations and medication use, not chronically ill.
- Intervention and comparison: LNF and 90° and/or 180° laparoscopic anterior fundoplication.
- 5 years follow-up.
- Outcome data: reflux control (heartburn and/or PPIs), complications (dysphagia for solids and/or reoperation), and satisfaction being dichotomous or able to convert. Satisfaction was defined as choosing surgery again or believed right to undergo.
- Full-text article published in English or Swedish in a peer-reviewed journal.

**Search methods and selection of studies**

Medline (Ovid), Embase, CINAHL, Cochrane Library, and Web of Science were systematically searched by medical information experts at the Karolinska Institutet library to identify relevant studies up to April 2020 (for keywords, see supplementary material). Reference lists of the included studies as well as relevant reviews were scanned for additional references. After removal of duplicates, the authors first independently screened and assessed the eligibility of titles/abstracts and then of the full-text articles. Excluded studies were stored for future reference, together with reasons for excluding. The study was considered the unit of interest. Disagreement was resolved through discussions.

**Data extraction and analysis**

The following data were extracted: methods (aim, study period, setting, recruitment, eligibility criteria), participants (number assessed for eligibility and randomized, age, gender), intervention, comparator, outcomes (assessments, timepoint/s, events, sample size). Each study was assessed for bias by both authors using the Cochrane Collaboration’s assessment tool [22]. Dichotomous outcome data were collated, and percentages recalculated as numbers. Meta-analyses were performed in Review Manager [23], using risk ratio (RR) as the effect measure in a random-effects model with an inverse variance statistical method, and significance level 0.05. Analyses were performed for each outcome separately, using the available case analysis with no imputation. In case of missing data, or for clarification, study authors were contacted. Subgroup analyses were performed for each outcome measure (dysphagia, mediation use, heartburn, reoperation, satisfaction) to compare laparoscopic anterior 90° fundoplication and laparoscopic anterior 180° fundoplication separately with LNF. This was done to see if an association was found between LNF and both fundoplication methods or LNF and one of the methods. To quantify the effect of heterogeneity, we used I² interpreted using the thresholds presented
Fig. 2 Risk of bias in included studies. + low risk of bias, - high risk of bias, ? unclear risk of bias

in the Cochrane handbook [22]. If considerable heterogeneity was identified, subgroup analyses were performed. Bias in meta-analyses was not assessed due to the low number of studies [22, 24].

Results

The database search identified 2137 records, an additional 10 were identified through review of references, and 1359 remained after removal of duplicates. After scanning titles and/or abstracts, 120 full-text articles were assessed for eligibility. In total, four studies met the eligibility criteria and were included in this review [25–28]. Scanning the reference lists of the included studies did not provide any additional studies of interest. The selection process is presented as a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram in Fig. 1.

Included studies

Included studies were published between 2005 and 2012 and the intervention groups included 194 participants and the comparator groups 204 participants (Table 1). Ludemann et al. reported that the fundus during the laparoscopic anterior 180° fundoplication was sutured to the right crus muscle [26]. This was not reported in Cao et al. [25].

The risks of biases are summarized in Fig. 2 and were mostly low except for selective reporting. The assessment of each study was based on the discrepancy between the reported information in the methods and the results sections. Some studies failed to report on outcomes mentioned in the methods section, while others presented results for outcomes which were omitted from the methods. None of the studies were assigned to have a high risk of bias in more than one domain.

Effects of intervention

Dysphagia

Dysphagia for solids was presented in three studies [26–28]. LNF treatment had a statistically significantly higher risk of dysphagia compared to laparoscopic anterior 90° and 180° fundoplication (RR 1.68 [1.14, 2.49], I² = 25%; Fig. 3). The possible subgroup analysis performed, using data from the two studies on LNF versus laparoscopic anterior 90° fundoplication [27, 28], showed a similar result, though not statistically significant (RR 1.73 [0.95, 3.17], I² = 61%).

Medication use

The included studies reported less PPI use in the LNF group (8% versus 16%). Albeit in favor of LNF, this difference was not statistically significant (RR 0.60 [0.19, 1.96], I² = 66%; Fig. 4). In the subgroup analysis, LNF was associated with a statistically significantly lower risk of medication use compared to laparoscopic anterior 90° fundoplication (RR 0.23 [0.09, 0.58], I² = 0%) [27, 28]. The other subgroup analysis was not statistically significant (RR 1.62 [0.59, 4.43], I² = 0%) [25, 26].

Heartburn

There were lower rates, but not statistically significantly (RR 0.86 [0.58, 1.26], I² = 11%), of heartburn after LNF (22% versus 26%; Fig. 5). Similar results were displayed in the subgroup analyses comparing LNF with laparoscopic anterior fundoplication of 90° (RR 0.92 [0.51, 1.68], I² = 48%) [27, 28] or 180° (RR 0.74 [0.35, 1.55], I² = 18%) [25, 26].

Reoperation

Reoperation was reported in all included studies. However, one study was omitted from the meta-analysis as a default function in Review Manager [27]. There was no statistically significant difference between LNF and the comparator group (RR 1.01 [0.43, 2.36], I² = 0%; Fig. 6). The feasible subgroup analysis, using data from two studies [25, 26], showed no statistically significant difference between LNF and laparoscopic anterior 180° fundoplication (RR 0.87 [0.30, 2.50], I² = 0%).
Fig. 3  Risk of dysphagia (for solids) 5 years after treatment. *LNF* Laparoscopic Nissen fundoplication, *IV* Inverse variance, *CI* Confidence interval

| Study or Subgroup | LNF Events | Comparator Events | Event Total | Weight | Risk Ratio IV, Random, 95% CI | Risk Ratio IV, Random, 95% CI |
|-------------------|------------|-------------------|-------------|--------|-------------------------------|-------------------------------|
| Ludemann 2005     | 14         | 51                | 9           | 50     | 23.1%                         | 1.53 [0.73, 3.20]             |
| Niljar 2010       | 18         | 44                | 17          | 53     | 38.9%                         | 1.28 [0.75, 2.20]             |
| Watson 2012       | 26         | 37                | 11          | 37     | 38.0%                         | 2.36 [1.38, 4.05]             |
| Total (95% CI)    | 132        | 140               | 100.0%      | 1.68   | [1.14, 2.49]                  |                               |
| Total events      | 58         | 37                |             |        |                               |                               |
| Heterogeneity: Tau² = 0.03, Chi² = 2.66, df = 2 (P = 0.27), I² = 25% | | | | | | |
| Test for overall effect: Z = 2.59 (P = 0.009) | | | | | | |

Fig. 4  Risk of medication use (proton pump inhibitors) 5 years after treatment. *LNF* Laparoscopic Nissen fundoplication, *IV* Inverse variance, *CI* Confidence interval

| Study or Subgroup | LNF Events | Comparator Events | Event Total | Weight | Risk Ratio IV, Random, 95% CI | Risk Ratio IV, Random, 95% CI |
|-------------------|------------|-------------------|-------------|--------|-------------------------------|-------------------------------|
| Cao 2012          | 4          | 47                | 4           | 49     | 25.6%                         | 1.04 [0.28, 3.93]             |
| Ludemann 2005     | 6          | 51                | 2           | 50     | 22.9%                         | 2.94 [0.62, 13.89]            |
| Niljar 2010       | 2          | 44                | 13          | 53     | 24.3%                         | 0.19 [0.04, 0.78]             |
| Watson 2012       | 3          | 37                | 11          | 37     | 27.3%                         | 0.27 [0.08, 0.90]             |
| Total (95% CI)    | 179        | 189               | 100.0%      | 0.60   | [0.19, 1.96]                  |                               |
| Total events      | 15         | 30                |             |        |                               |                               |
| Heterogeneity: Tau² = 0.06, Chi² = 8.91, df = 3 (P = 0.03), I² = 66% | | | | | | |
| Test for overall effect: Z = 0.84 (P = 0.40) | | | | | | |

Fig. 5  Risk of heartburn 5 years after treatment. *LNF* Laparoscopic Nissen fundoplication, *IV* Inverse variance, *CI* Confidence interval

| Study or Subgroup | LNF Events | Comparator Events | Event Total | Weight | Risk Ratio IV, Random, 95% CI | Risk Ratio IV, Random, 95% CI |
|-------------------|------------|-------------------|-------------|--------|-------------------------------|-------------------------------|
| Cao 2012          | 8          | 47                | 8           | 49     | 17.5%                         | 1.04 [0.43, 2.55]             |
| Ludemann 2005     | 5          | 51                | 10          | 50     | 14.2%                         | 0.49 [0.18, 1.33]             |
| Niljar 2010       | 12         | 44                | 21          | 53     | 36.9%                         | 0.69 [0.30, 1.24]             |
| Watson 2012       | 14         | 37                | 11          | 37     | 31.4%                         | 1.27 [0.67, 2.43]             |
| Total (95% CI)    | 179        | 189               | 100.0%      | 0.86   | [0.58, 1.26]                  |                               |
| Total events      | 39         | 50                |             |        |                               |                               |
| Heterogeneity: Tau² = 0.02, Chi² = 3.36, df = 3 (P = 0.34), I² = 11% | | | | | | |
| Test for overall effect: Z = 0.79 (P = 0.43) | | | | | | |

Fig. 6  Reoperation 5 years after treatment. *LNF* Laparoscopic Nissen fundoplication, *IV* Inverse variance, *CI* Confidence interval

| Study or Subgroup | LNF Events | Comparator Events | Event Total | Weight | Risk Ratio IV, Random, 95% CI | Risk Ratio IV, Random, 95% CI |
|-------------------|------------|-------------------|-------------|--------|-------------------------------|-------------------------------|
| Cao 2012          | 3          | 47                | 4           | 49     | 34.6%                         | 0.78 [0.18, 3.31]             |
| Ludemann 2005     | 3          | 51                | 3           | 50     | 29.9%                         | 0.98 [0.21, 4.63]             |
| Niljar 2010       | 0          | 44                | 0           | 53     | Not estimable                 |                              |
| Watson 2012       | 4          | 37                | 3           | 37     | 35.4%                         | 1.33 [0.32, 5.55]             |
| Total (95% CI)    | 179        | 189               | 100.0%      | 1.01   | [0.43, 2.36]                  |                               |
| Total events      | 10         | 10                |             |        |                               |                               |
| Heterogeneity: Tau² = 0.00, Chi² = 0.27, df = 2 (P = 0.87), I² = 0% | | | | | | |
| Test for overall effect: Z = 0.03 (P = 0.99) | | | | | | |

**Satisfaction**

Satisfaction was similar between the groups and the meta-analysis showed no statistically significant difference (RR 0.97 [0.90, 1.05], I² = 0%; Fig. 7). The subgroup analyses demonstrated similar results, irrespective of solely comparing with 90° (RR 1.01 [0.86, 1.18], I² = 32%) [27, 28] or 180° (RR 0.95 [0.86, 1.04], I² = 0%) [25, 26].

**Heterogeneity**

Most meta-analyses showed an I² value 0–25%, indicating that heterogeneity was unlikely to be important.
An exception was the meta-analysis for medication use, with an $I^2$ value of 66%, which may represent substantial heterogeneity. However, the two subgroup analyses presented $I^2$ values of 0%, meaning that the heterogeneity in the overall analysis was most likely explained by the subgroup analyses.

**Discussion**

**Summary of main results**

We found no statistically significant difference in reflux control between LNF and laparoscopic anterior 90° or 180° fundoplication measured by heartburn and PPI use, albeit results in favor of LNF. However, subgroup analysis indicated a significantly lower use of medication after LNF than laparoscopic anterior 90° fundoplication. Furthermore, there was significantly higher risk of dysphagia for solids after LNF than in patients who underwent laparoscopic anterior 90° or 180° fundoplication. Subgroup analysis of LNF versus laparoscopic anterior 90° fundoplication regarding dysphagia showed borderline significant results due to low numbers. Reoperation and satisfaction rates were equivalent between procedures. In summary most differences were between LNF and laparoscopic anterior 90° fundoplication, highly likely related to the evident differences in fundoplication degree.

**Quality of evidence**

The risk of bias was assessed as unclear in several instances, mostly in the random sequence generation and in outcomes of interest. Included studies provided inadequate information about some important contextual and cultural factors, affecting the generalizability.

**Comparison with findings from other studies**

To our knowledge, no previous systematic review and meta-analysis has investigated reflux control, complications, and satisfaction at the five-year follow-up in GERD patients who underwent LNF or laparoscopic anterior 90°/180° fundoplication. Our results regarding higher rates of dysphagia are consistent with previous findings, although our focus was on dysphagia for solids [8–10, 12, 19]. Unlike the present findings, no differences in medication use were displayed in several studies [9, 10, 19]. Reflux control in terms of heartburn was reported in previous reviews, where some indicated no differences [9, 10, 19] and others demonstrated results in favor of LNF [8, 12]. However, these reviews compared LNF to more treatment options than the ones used in the present study. Two reviews reported no differences in reoperation rates, as seen in our results [9, 10]. As in the present study, high patient satisfaction, regardless of treatment, was reported in two previous reviews [10, 19].

**Strengths and limitations of the present study**

Bias across studies was not possible to assess and cannot therefore be ruled out [22, 24]. A potential major risk of bias is related to selective outcome reporting, since presented results often differed from stated methods.

**Implications and conclusion**

Ideally, a surgical procedure would have high reflux control and few complications among satisfied patients. When considering the different outcomes of a procedure, the review findings indicate a trade-off between reflux control and complications. At 5-year follow-up, patients who received LNF reported significantly less medication use than those who had 90° fundoplication. However, more dysphagia for solids was reported after LNF compared to 90° and 180° fundoplication. There was not enough evidence to detect significant differences in terms of heartburn, reoperation, and satisfaction after 5 years. The limited evidence fails to provide an unequivocal method of choice for GERD patients, but rather indicates what would be expected, namely a tradeoff between reflux control and complications. The results of the present review suggest that more trials need to be done to provide consistent evidence.

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**Conflict of interest** J. Hofsten is a consultant for Implantica, however, Karolinska Institutet has full data ownership as specified in the funding contract. Y. Forsell declares that she has no competing interests.

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