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Review

Does the addition of a fundoplication improve outcomes for patients undergoing laparoscopic Heller's cardiomyotomy?

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ABSTRACT

Laparoscopic Heller's cardiomyotomy is a well-established technique in the treatment of achalasia. However, the addition of a routine fundoplication as part of this procedure remains controversial. A best evidence topic in upper gastrointestinal surgery was written according to a structured protocol. The question addressed whether the addition of a fundoplication improved clinical outcomes. Two hundred and seven papers were found using the reported search and of these, 8 papers were identified using a pre-determined criteria as representing the best answer to this clinical question. There were 2 meta-analyses, 3 randomised controlled trials and 3 prospective series. The author, journal, date and country of publication, patient group, study type, relevant outcomes, results, and study weaknesses of these papers are tabulated. Review of the data shows that the rates of gastro-oesophageal reflux both on pH monitoring and symptom reporting are all reduced when an anti-reflux procedure is added to a Heller's cardiomyotomy. In terms of the choice of the anti-reflux procedure, comparison between the Dor anterior and Toupet posterior fundoplications do not show any obvious clinical differences, however dysphagia appears to be lower in those undergoing partial fundoplication as compared to a Nissen fundoplication.

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1. Introduction

A best evidence article was constructed according to a structured protocol as described in a previous publication in the *International Journal of Surgery*.¹

2. Clinical scenario

You are in the outpatient clinic with a 35 year old male patient who has achalasia and is scheduled for a laparoscopic Heller's cardiomyotomy. He has been reading about the surgical options on the internet and asks whether a fundoplication will be part of the planned procedure. You decide to check the recent literature to determine whether a laparoscopic Heller's cardiomyotomy combined with an anti-reflux procedure is associated with better outcomes compared with a laparoscopic Heller's cardiomyotomy alone.

3. Three-part question

In [patients undergoing laparoscopic Heller's cardiomyotomy for achalasia] does the addition of a [fundoplication] improve [outcomes]?

4. Search strategy

Medline search 1990–2011 using the Pubmed interface for the terms: achalasia [All Fields] AND myotomy OR cardiomyotomy OR ("fundoplication" [MeSH Terms] OR "fundoplication"[All Fields]) OR ("fundoplication"[MeSH Terms]) was performed.

5. Search outcome

207 papers were found using the described search technique. Abstracts were searched and papers which included thoracoscopic or thoracotomy approaches, open abdominal surgery and paediatric population were discarded. The remaining meta-analyses and prospective and retrospective studies comparing the outcomes of

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Table 1
Best evidence papers.

Author, date and country	Patient group	Study type (level of evidence)	Outcomes	Key results	Comments
Lyass et al., 2003, USA ²	Meta-analysis of the effect of anti-reflux procedures after laparoscopic Heller's myotomy (21 studies from 1995–2000) LHM <i>n</i> = 532 LHM <i>n</i> = 69	Meta-analysis (level 1)	Post myotomy GOR symptoms rate Post myotomy GOR rate based on pH manometry Post myotomy dysphagia rates	5.9% LHM 13% LHM <i>p</i> = 0.12 7.9% LHM 10% LHM <i>p</i> = 0.75 3.2% LHM 1.5% LHM No <i>p</i> value given	This meta-analysis has been superseded by the Campos et al. study. It has several criticisms: it included mainly retrospective studies. It contains low patient numbers for those who did not have an additional anti-reflux operation (<i>n</i> = 69). Few patients had assessment by 24 h pH studies (only 18 out of 228 patients). There was heterogeneity in surgical technique (80.6% had Dor and 19.4% had Toupet fundoplication).
Richards et al. 2004 USA ³	A prospective randomised trial of 43 patients comparing LHM (<i>n</i> = 21) with a LHM (<i>n</i> = 22) in the form of an anterior Dor fundoplication	RCT (level 2)	Post myotomy GOR symptom rate Post myotomy GOR rate based on pH manometry Post-operative dysphagia and lower oesophageal pressure Median acid exposure time (per 24 h)	Not specifically measured by study 9.1% LHM 47.6% LHM <i>P</i> = 0.0005 No significant difference between groups 0.4% LHM 4.9% LHM <i>P</i> = 0.001	A well designed randomised controlled trial which provides Level 2 evidence that the addition of a Dor anterior fundoplication is beneficial for reflux control and does not worsen post-operative dysphagia. However, the trial has small patient numbers and looked mainly at pH studies outcome rather than symptomatic reporting of GOR symptoms. FU was less than 6 months.
Tapper et al., 2008, USA ⁴	Prospective comparative study comparing 174 patients LHM (1992–2004) and 137 patients LHM (2004–2007)	Prospective study (level 3)	Post-operative symptomatic GOR Other post-operative symptoms Patient symptom resolution (excellent or good) Requirement for repeat intervention for recurrent symptoms of achalasia	Greater reduction on symptoms in the LHM group Dysphagia & choking were significantly less frequent in the LHM group 75% LHM 89% LHM No <i>p</i> value 4% LHM 11% LHM No <i>p</i> value	This large-scale study did not rely on any objective measurements of outcomes, but instead used a patient rated scoring system. Post-operative heartburn, dysphagia & choking were significantly less frequent in the LHM group. However patient satisfaction was higher in LHM alone group. It should be noted there was some disparity in the two groups with an increased pre-operative frequency of symptoms and younger age in the LHM alone group.
Campos et al., 2009, USA ⁵	Meta-analysis including 39 papers with 3086 patients having lap myotomy from 1995 to 2006	Meta-analysis (level 1)	Post myotomy GOR rate based on symptoms Post myotomy GOR rate based on pH manometry. Symptom improvement	8.8% LHM 31.5% LHM <i>P</i> = 0.003 14.5% LHM 41.5% LHM <i>P</i> = 0.01 90.3% (77–100%) LHM 89.9% (86–100%) LHM No <i>p</i> value	Main findings were that the addition of a fundoplication decreases pathological GOR after myotomy and resolution of dysphagic symptoms is independent of whether a fundoplication is performed. Criticisms include the small patient numbers included in original papers analysed, study heterogeneity in terms of surgical technique (wrap type used) and retrospective nature of a large proportion of the studies included.
Wills et al., 2001 Australia ⁶	62 patients with achalasia who had LHM with Nissen fundoplication (<i>m</i> = 49) and LHM with partial 120° fundoplication (<i>n</i> = 13)	Prospective series (level 3)	Dysphagia score 3 years Dysphagia score 5 years Chest pain score	Non-significant difference <i>P</i> = 0.36 Trend for worse result in Nissen group <i>P</i> = 0.08 2.2 Nissen group 0.8 Partial group <i>P</i> = 0.002	This study showed a trend for worse dysphagia and chest pain scores for patients treated with a Heller's cardiomyotomy and Nissen fundoplication. Presented graphically in the paper is a worrying trend for worsening dysphagia scores in the Nissen group between 5 and 7 years post-operatively.
Rebecchi et al., 2008, Italy ⁷	144 patients with achalasia randomised to either LHM with either an anterior Dor (<i>n</i> = 72) or Nissen fundoplication (<i>n</i> = 72)	RCT (level 2)	Post myotomy GOR rate based on symptoms at 60 months. Post myotomy GOR rate based on pH studies at 60 months. Post myotomy dysphagia rates with at 60 months	5.6% Dor 0% Heller <i>P</i> = 0.07 2.8% Dor 0% Heller No <i>p</i> Value 2.8% Dor 15% Heller <i>P</i> < 0.001	Long follow-up (125 months) is a benefit of this paper. The main findings are that recurrence of dysphagia is more frequent in patients who have a Nissen fundoplication. This paper supports the use of an anterior Dor fundoplication as the preferred method to control post-operative reflux in patients undergoing laparoscopic Heller's myotomy
Rawlings et al., 2011, USA ⁸	85 patients with achalasia randomised to either LHM with Dor fundoplication (<i>n</i> = 36)	Multicentre RCT (level 2) 5 university hospitals	Post myotomy GOR rate based on pH studies (% total time pH < 4)	2.5% Dor 0.6% Toupet <i>P</i> = 0.582 41.7% Dor	Underpowered study (sample size of 49 patients was required in each arm to reveal a 20% difference in reflux rates). Symptomatic evaluation and pH testing was

Table 1 (continued)

Author, date and country	Patient group	Study type (level of evidence)	Outcomes	Key results	Comments
	or Toupet fundoplication (<i>n</i> = 24). 25 original randomised patients were excluded due to lack of follow-up evaluation		Post myotomy GOR rate DeMeester score > 14.7 Overall percentage improvement in symptoms	21.1% Toupet <i>P</i> = 0.152 90.9% Dor 93.1% Toupet No <i>p</i> Value	incomplete and led to exclusion of 25 patients. Overall, there were no statistically significant differences between the two groups. However, there was a non-statistical trend for abnormal post-operative pH studies results in the Dor fundoplication group.
Martino et al., 2011, Italy ⁹	56 patients with achalasia; 30 had laparoscopic Heller's cardiomyotomy with anterior Dor fundoplication and 26 had calibrated Nissen–Rossetti fundoplication	Prospective study (Level 3)	Post-op QOL Median post-op LOS pressure Post-op median dysphagia score % patients with abnormal GOR Median % time < pH 4 post-op pH manometry	No statistical difference 18 (7–22) mmHg Dor 22.5 (20–29) mmHg Nissen <i>P</i> = 0.91 3 (range 0–5) Dor 3 (range 0–5) Nissen <i>P</i> = 0.91 13.3% (3/30) Dor 0% (0/26) Nissen <i>P</i> = 0.11 2 (0.8–10) Dor 0.35 (0–2) Nissen <i>P</i> < 0.0001	This is a prospective comparison between an additional Nissen–Rossetti fundoplication performed between April 2003 and April 2005 and additional Dor anterior partial fundoplication performed between May 2005 and May 2007. Operative technique was to calibrate the wrap by using intra-operative endoscopy and manometry. Follow-up was limited to 24 months. The study was underpowered to assess the differences in post-operative reflux.

LHM: laparoscopic Heller's cardiomyotomy, LHMF: laparoscopic Heller's cardiomyotomy + fundoplication, GOR: Gastro-oesophageal reflux, RCT: randomised controlled trial, LOS = lower oesophageal sphincter pressure.

laparoscopic Heller's cardiomyotomy with and without fundoplication were then reviewed and following elimination of duplicate studies included in the meta-analyses, a total of eight papers were selected as representing the best evidence to answer this clinical question.

6. Results

The results of the eight papers are summarised in Table 1.

7. Discussion

Although Heller's cardiomyotomy is a well-established surgical treatment for achalasia, there is no agreement as to whether a fundoplication should be routinely added to this procedure. Advocates of routine fundoplication argue that this prevents long-term gastro-oesophageal reflux (GOR), whilst others apply a more selective approach, offering fundoplication only to those with pre-operative symptoms of reflux. In addition, some surgeons argue that patients undergoing a thoracic approach and hence (for technical reasons) having a shorter gastric myotomy do not require fundoplication.

With respect to laparoscopic approach, Lyass et al.² performed a meta-analysis and found no statistical differences between the results of pH studies or gastro-oesophageal reflux symptoms after surgery in patients who had a laparoscopic Heller's myotomy with or without a fundoplication. However, this meta-analysis has several criticisms. For a start there was a large difference in the size of the two groups (532 in the fundoplication group and 69 without fundoplication). In addition, most of the studies included in the analysis were retrospective; there was significant heterogeneity in the technique of fundoplication and other symptoms such as dysphagia were not assessed. Nevertheless, in sub-group analysis (performed by excluding those studies which did not utilise objective pH studies) the post-operative GOR rates with and without fundoplication were 2.7% vs. 13% respectively (*p* = 0.01), supporting the addition of a fundoplication.

Richardset al. performed the only randomised trial on this topic which included 43 patients randomised to laparoscopic Heller's cardiomyotomy with or without anterior partial fundoplication.³ Patients returned for oesophageal manometry and 24 h pH monitoring at 3–5

months post procedure. A questionnaire looking at severity and frequency of symptoms of dysphagia was also performed prior to manometry and pH assessment. Pathological GOR on pH studies was shown in 10 of 21 patients (47.6%) with Heller's cardiomyotomy alone and 2 of 22 patients (9.1%) with Heller's cardiomyotomy plus fundoplication (*p* = 0.005). This study also noted no differences in lower oesophageal sphincter pressure or post-operative dysphagia score between the two groups.

Tapper et al. (from the same surgical department as Richards et al.³) published a retrospective review of all their patients undergoing laparoscopic Heller's cardiomyotomy.⁴ Prior to 2004 they did not perform a fundoplication, whilst after the results of their randomised controlled trial they routinely added an anterior Dor fundoplication. The study did not include any objective measurements of reflux but instead reported Likert scores of dysphagia, heartburn, vomiting, choking and chest pain. They found improved symptom control with reduced rates of dysphagia and heartburn in those with a fundoplication. However, the two groups were significantly different- the group without fundoplication was younger and had a higher frequency of all symptoms, so it is possible that these factors could influence the results.

A systematic review dealing with a number of aspects of achalasia management was published in 2009 by Campos et al.⁵ including articles published between 1975 and 2006. Of interest the authors of this meta-analysis chose not to include Richards et al. study because they excluded studies with less than 6 months follow-up and their search strategy predated the publication of the Tapper et al. study.⁴ This study had several parts with a specific section looking at the results of laparoscopic Heller's cardiomyotomy with and without fundoplication. This section included 39 papers (20 prospective and 19 retrospective studies) with a mean follow-up of 35 months. Overall symptom improvement did not change with the addition of a fundoplication however the incidence of post-operative GOR symptoms was lower in patients who had a fundoplication. Regression analysis for the subset of papers which measured GOR using objective testing confirmed a lower rate of acid in the oesophagus. There was no difference in the rate of post-operative dysphagia between the groups.

On reviewing the results of these two meta-analyses, randomised controlled trial and prospective study all suggest that the addition of an anti-reflux procedure is of clinical benefit. However,

what these studies do not definitively demonstrate is which type of fundoplication leads to the best clinical outcome. Two randomised studies and two prospective series have specifically looked at this question.

Wills et al. reported on a prospective cohort comparison study of 62 patients who underwent Heller's cardiomyotomy⁶ with routine fundoplication. The majority of these were performed laparoscopically, however seven were converted to open and four were elective open procedures. Early in the series an anterior 120° fundoplication ($n = 13$) was used, whilst the majority of patients had a Nissen (360°) fundoplication ($n = 49$). Chest pain scores were significantly worse in the Nissen group and there was trend for worse long-term dysphagia scores.

Di Martino et al. conducted a prospective study assessing 56 patients who had a Heller's cardiomyotomy with either a 180° anterior partial fundoplication or a Nissen 360° fundoplication.⁹ There was no difference in operative times ($p = 0.67$) or post-operative quality of life (QoL) measures, nor any differences in dysphagia scores. Although the study was underpowered to assess differences in symptomatic post-operative reflux, there was a trend for less abnormal post-operative reflux in the Nissens group.

Rebecchi et al. conducted a prospective randomised trial of 144 patients comparing an anterior partial fundoplication with a total Nissen fundoplication following laparoscopic Heller's myotomy.⁷ They found that reflux symptoms were lower in patients undergoing a Nissen fundoplication as compared to a Dor fundoplication at 60 months; however these differences were not statistically significant. There was however a significantly higher gastro-oesophageal sphincter pressure in the Nissen group along with a significantly increased rate of dysphagia.

Rawlings et al. performed a randomised control trial comparing patients undergoing laparoscopic myotomy with either a Dor anterior fundoplication or Toupet posterior fundoplication.⁸ They found that both types of fundoplication were able to achieve reflux control. Of interest there was a trend for increased reflux in the Dor group compared with the Toupet fundoplication group. However, this did not reach statistical significance and the findings should be interpreted with caution as the study is underpowered and a significant proportion of patients did not attend for follow-up evaluation.

8. Clinical bottom line

Routine fundoplication following laparoscopic Heller's cardiomyotomy reduces the incidence of pathological gastro-oesophageal

reflux after surgery. Although the evidence base is limited, the current literature supports the addition of a partial fundoplication rather than a total fundoplication to avoid the risk of dysphagia.

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Conflicts of interest

None.

Author contribution

Damian Mayo – Literature search, analysis, writing
 Ewen Griffiths – Literature search, analysis, writing
 Omar Khan – Analysis and editing of manuscript
 Mark Szymankiewicz – Analysis and editing of manuscript
 Christian Wakefield – Analysis and editing of manuscript
 Sarah Thompson – Analysis and editing of manuscript

References

1. Khan OA, Dunning J, Parvaiz AC, Agha R, Rosin D, Mackway-Jones K. Towards evidence-based medicine in general surgical practice: best BETs. *Int J Surg* 2011;**9**:585–8.
2. Lyass S, Thoman D, Steiner JP, Phillips E. Current status of an antireflux procedure in laparoscopic Heller myotomy. *Surg Endosc* 2003;**17**:554–8.
3. Richards WO, Torquati A, Holzman MD, Khaitan L, Byrne D, Lutfi R, et al. Heller myotomy versus Heller myotomy with Dor fundoplication for achalasia: a prospective randomized double-blind clinical trial. *Ann Surg* 2004;**240**:405–12.
4. Tapper D, Morton C, Kraemer E, Villadolid D, Ross SB, Cowgill SM, et al. Does concomitant anterior fundoplication promote dysphagia after laparoscopic Heller myotomy? *Am Surg* 2008;**74**:626–33.
5. Campos GM, Vittinghoff E, Rabl C, Takata M, Gadenstatter M, Lin F, et al. Endoscopic and surgical treatments for achalasia: a systematic review and meta-analysis. *Ann Surg* 2009;**249**:45–57.
6. Wills VL, Hunt DR. Functional outcome after Heller myotomy and fundoplication for achalasia. *J Gastrointest Surg* 2001;**5**:408–13.
7. Rebecchi F, Giaccone C, Farinella E, Campaci R, Morino M. Randomized controlled trial of laparoscopic Heller myotomy plus Dor fundoplication versus Nissen fundoplication for achalasia: long-term results. *Ann Surg* 2008;**248**:1023–30.
8. Rawlings A, Soper NJ, Oelschlager B, Swanstrom L, Matthews BD, Pellegrini C, et al. Laparoscopic Dor versus Toupet fundoplication following Heller myotomy for achalasia: results of a multicenter, prospective, randomized-controlled trial. *Surg Endosc* 2011 Jul 26 [Epub].
9. Di Martino N, Brillantino A, Monaco L, Marano L, Schettino M, Porfidia R, et al. Laparoscopic calibrated total vs partial fundoplication following Heller myotomy for oesophageal achalasia. *World J Gastro* 2011;**17**:3431–40.