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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 rate 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

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