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Almond, L.m.; Charalampakis, V.; Mistry, P.; Hodson, James; Lafaurie, G.; Matthews, J.; Singhal, Rishi; Super, P.

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Accepted Manuscript

An "all 5mm ports" technique for laparoscopic day-case anti-reflux surgery: A Consecutive Case Series of 205 Patients

Mr L.M. Almond, V. Charalampakis, P. Mistry, J. Hodson, J. Matthews, R. Singhal, P. Super



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Title

An "all 5mm ports" technique for laparoscopic day-case anti-reflux surgery: A Consecutive Case Series of 205 Patients

Authors and Affiliations

LM Almond¹, V Charalampakis¹, Mistry P¹, J Hodson², J Matthews¹, R Singhal¹, P Super¹.

¹Department of Upper Gastrointestinal Surgery, Heart of England NHS Foundation Trust

²Department of Medical Statistics, University of Birmingham

Corresponding Author

Mr LM Almond
Department of Upper Gastrointestinal Surgery
Heart of England NHS Foundation Trust
Heartlands Hospital
Bordesley Green East
Birmingham
B9 5SS
Email: mxa891@hotmail.com
Tel: 0121 4242000
Fax: 0121 4240507

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Abstract

Introduction: Laparoscopic anti-reflux surgery is conventionally performed using two 10/12 mm ports. While laparoscopic procedures reduce post-operative pain, the use of larger ports invariably increases discomfort and affects cosmesis. We describe a new all 5 mm ports technique for laparoscopic anti-reflux surgery and present a review of our initial experience with this approach.

Methods: All patients undergoing laparoscopic fundoplication over a 35 month period from February 2013 under the care of a single surgeon were included. A Lind laparoscopic fundoplication was performed using an all 5mm port technique. Data was recorded prospectively on patient demographics, operating surgeon, surgical time, date of discharge, readmissions, complications, need for re-intervention, and reasons for admission.

Results: Two hundred and five consecutive patients underwent laparoscopic fundoplication over the study period. The all 5 mm port technique was used in all cases, with conversion to a 12 mm port

only once (0.49 %). Median operating time was 52 minutes. 185 (90.2 %) patients were discharged as day cases. Increasing ASA grade and the presence of a hiatus hernia were associated with the need for overnight stay with admission required in 33 % of patients with ASA 3, compared to 4 % with ASA 1 ($p=0.001$), and 29 % of those with a hiatus hernia vs. 5 % without ($p<0.001$). No port-related complications occurred, and no patients developed recurrence of reflux symptoms. A single patient required mesh repair of a large hiatus hernia.

Conclusion: The all 5 mm ports approach to laparoscopic anti-reflux surgery is a safe, efficient, and cost-effective technique which facilitates same day discharge and minimises port related complications. National commissioning guidelines in the UK should target quality improvements in anti-reflux surgery based around day-case management. This would improve the service for these patients and culminate in cost savings for the NHS.

Keywords

Anti-reflux surgery, laparoscopic fundoplication, gastro-oesophageal reflux disease, port-site complications

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Introduction

Laparoscopic fundoplication is the standard of care for patients with refractory gastro-oesophageal reflux disease (GORD) particularly those with volume symptoms and chronic respiratory complications.^{1,2} Surgery also prevents the need for lifelong proton pump inhibitor therapy in patients with symptomatic GORD, with effective control of symptoms in up to 88% of patients at 5 years.²⁻⁶

Increasingly commissioners are seeking cost efficient services that are delivered with low morbidity and short hospital stays.⁷ Traditional open anti-reflux surgery was frequently associated with wound and respiratory complications leading to prolonged admission.^{8,9} However, the advent of laparoscopic fundoplication has reduced this morbidity significantly, and facilitated early discharge.¹⁰ Day-case laparoscopic anti-reflux surgery is now widely practiced and has been shown to result in similar long-term functional and quality of life outcomes compared to an inpatient approach, but with a considerable cost saving.^{11,12} Despite this, day case rates for anti-reflux surgery in England remain under 10 % with an average length of stay of 2.7 days (5).¹³

Recently, combined guidance from the Association of Upper Gastrointestinal Surgeons (AUGIS) and the Royal College of Surgeons of England (RCS) has recommended that commissioners introduce financial incentives for Trusts that provide a day-case service and are able to demonstrate a median length of stay of one day following anti-reflux surgery.⁷

Laparoscopic anti-reflux surgery is conventionally performed with the use of two 10/12mm ports. The reported incidence of port site complications following laparoscopic surgery varies between 0.2% and 6% with the use of larger ports being associated with increased post-operative pain as well as a higher risk of port-site bleeding and herniation.¹⁴ A recent randomised trial comparing an “all 5mm ports” versus a conventional ports approach to laparoscopic fundoplication demonstrated that the all 5mm port technique was safe, and achieved improved cosmetic results and patient acceptability.¹⁵ The present consecutive case series reports single surgeon outcomes using an all 5 mm ports technique for laparoscopic anti-reflux surgery with the aim of maximising day-case rates and minimising post-operative wound related morbidity.

Patients and Methods

Consecutive patients undergoing laparoscopic anti-reflux surgery under the care of a single surgeon using an all 5mm port technique between February 2013 and January 2016 are included. Data was recorded prospectively and included patient demographics, indication for surgery, surgeon, duration of surgery, length of hospital stay, readmission rates, need for post-operative re-intervention, and port site complications. Prior to analysis, all data were corroborated by retrospective review of electronic case records. All patients were reviewed post-operatively at 12 weeks.

Surgical Technique

The all 5mm port technique was employed unselectively in all cases utilising a high-definition 5mm camera. The dissection, hiatal repair and fundoplication were performed using a standardised, Lind partial fundoplication technique which has successfully been adopted in our unit since 1999 in over 1300 cases. No changes were made to the operative procedure as previously described.¹⁶

Pneumoperitoneum was established using Veress needle insufflation at the left costal margin and the left lateral lobe of the liver was retracted to allow access to the hiatus. Hiatal dissection was performed using hook diathermy only, ensuring at least 4cm of intra-abdominal oesophagus and with preservation of the crural epimysium. Advanced energy devices were not utilised for any of the cases. The short gastric vessels were never divided. Crural repair was completed using non-absorbable suture material taking care to avoid over-tightening of the crural defect. A bougie was not used for calibration in any case. Where a large hiatus hernia was encountered which prevented tension-free repair of the crural defect, a Bard CruraSoft hiatal patch was fixed to the crural margins. The mesh was inserted into the abdominal cavity by twisting it tightly over a Veress needle which was then inserted through a 5mm port.

In all cases a 300 degree subtotal posterior fundoplication (Lind) was performed leaving a bare area on the anterior oesophagus for the anterior vagus nerve which was carefully identified and preserved.^{16,17} The superior most suture on either side of the wrap was anchored to the hiatal margin and two further sutures on each side of the oesophagus completed the fundoplication (Figure 1).

All cases were performed by a single Consultant surgeon or a senior trainee with direct Consultant supervision. Patients were given a 100mg diclofenac suppository at the end of

the procedure unless contraindicated. Two hours after the procedure all patients received 40mg subcutaneous enoxaparin.

Statistical analysis

Continuous variables are reported as mean \pm SD, with comparisons between groups being made using t-tests. Fisher's exact tests were used for categorical variables. Comparisons with ASA were made using Kendall's Tau or Jonckheere–Terpstra tests, as applicable, in order to account for the ordinal nature of this factor. Pearson's r correlation coefficients were produced when comparing two continuous variables. All analyses were performed using IBM SPSS 22 (IBM Corp. Armonk, NY), with $p < 0.05$ deemed to be indicative of statistical significance throughout.

Results

Two hundred and five consecutive patients underwent laparoscopic fundoplication over the 35 month study period. The all 5mm port technique was used in all cases, with conversion to a 12mm port in one patient (0.49%) to permit insertion of a swab. The median age of patients was 51 years (range 19-81 years) and the majority were female (61.5%). 95(46.3%) cases were performed by a senior trainee under direct supervision of a single Consultant surgeon who performed the remaining 110(53.7%) cases. 35 (17.1%) patients had a sliding hiatus hernia, with a single patient (0.49%) requiring mesh insertion at the hiatus. There were no conversions to open surgery. Patient demographics and operative factors are reported in Table 1.

185 (90.2%) patients were discharged on the day of surgery. 17(8.3%) patients were discharged on the first post-operative day, and 1 (0.49%) patient each on day 2 and day 3. One patient was admitted for 7 days following an exacerbation of asthma. The causes for delayed discharge in these patients were post-operative nausea (3, 1.5%), pain (3, 1.5%), exacerbation of asthma (1, 0.49%), planned admission due to medical comorbidity (11, 5.3%), and a delayed start time causing a late finish (2, 0.97%).

Surgical and patient factors were correlated to length of stay data (Table 2). Patients with a hiatus hernia were more likely to require an overnight stay than those without (29% vs. 5%, $p < 0.001$). Increasing ASA grade was also associated with need for overnight stay with admission required in 33% of patients with ASA 3, compared to 4% with ASA 1 ($p = 0.001$).

Factors influencing operating time are reported in Table 3. The median operating time using the 5mm port technique was 52 minutes (range 26 - 113), which was significantly shorter when the surgery was undertaken by the Consultant as opposed to a trainee (45 Vs 64 minutes; $p < 0.001$). The Consultant operated on a larger proportion of patients with ASA 2/3 than the trainees, who operated on a higher proportion with ASA 1 ($p = 0.016$).

No intra-operative or immediate post-operative complications occurred. There were 6 readmissions within 30 days for pain (3, 1.5%), nausea (2, 0.97%) and dysphagia (1, 0.49%). After a median follow-up of 6 months, no patients required repeat surgical intervention, although 3 (1.5%) patients with persistent dysphagia at 6 weeks underwent a single endoscopic dilatation with successful outcome. No port-related complications occurred, and no patients developed recurrence of reflux symptoms.

Discussion

Day-case laparoscopic fundoplication is known to be safe, efficient, and cost-effective. Combined guidance from the Association of Upper Gastrointestinal Surgeons (AUGIS) and the Royal College of Surgeons of England (RCS) has recommended that commissioners provide financial incentives to encourage short post-operative stays following anti-reflux surgery.

Despite more than 70% of all elective surgery being performed laparoscopically in the UK, uptake of day case anti-reflux surgery has remained limited.¹⁸ Day case figures reported in the literature vary widely and higher rates have been attributed to case selection and publication bias. The Surgical Workload, Audit and Research Database (SWORD), maintained by AUGIS, has reported increasing day case rates in England with 5.5% of patients undergoing day case fundoplication in 2009-10 compared to 11.7% in 2014-15.¹⁹⁻²³ Our day case rate of 89% reported in this series for consecutive group of unselected patients compares very favourably to these data.

As well as an evolution in surgical mentality, it is a combination of organisational, patient-centred, anaesthetic, and surgical factors which are essential to establishing and maintaining an ambulatory service. These include meticulous pre-assessment including effective patient education, short surgical and anaesthetic times with limitation of post-operative nausea and vomiting (PONV), and minimisation of surgical trauma and intra-operative bleeding. Pain control must be optimised using a multimodal strategy. In the present series all patients received a diclofenac suppository at the end of the procedure unless contraindicated, in combination with local anaesthetic. The administration of stronger opiates, such as morphine was avoided in the post-operative period. In addition, 99.5% of cases were performed using an all 5mm port technique. These measures enabled a day-case rate of 90.2%. Increasing ASA grade and the presence of a hiatus hernia predisposed to an increased risk of overnight stay. These findings are consistent with previous series.^{18,24,25}

The present series describes the experience of a single surgeon and the results may therefore not be generalisable to a wider cohort. The length of follow-up was also relatively short, and the long-term incidence of recurrent reflux or port-site hernia cannot therefore be reported. There were however no short term port-related complications. It was not the aim of the present series to evaluate long-term control of reflux using the modified Lind fundoplication as these data have been reported previously.²⁴ Nevertheless, across a median follow-up of 6 months, there were no cases of recurrent reflux, or surgical re-intervention in the present series.

A previous study carried out at our unit over a ten year period demonstrated a failure rate of 1.6% (defined as recurrence of symptoms or hiatus hernia) after a 12 month follow up.²⁵ In this series which included 723 patients, there was a re-operation rate of 0.41% (3 patients) with one of those cases being drainage of a port site abscess. A single patient underwent a redo hiatus hernia repair and fundoplication within one year which compares very favourably to 12 month re-operation rates reported in the literature.²⁵

The all 5 mm ports approach to laparoscopic anti-reflux surgery is a safe, efficient, and cost-effective technique which facilitates same day discharge and minimises port related complications. National commissioning guidelines in the UK should target quality

improvements in anti-reflux surgery based around day-case management. This would improve the service for these patients and culminate in cost savings for the NHS.

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Table 1 – Demographics

Data reported as mean±SD or N (%), as applicable

*Based on N=199

Table 2 – Associations with Length of Stay

Data reported as mean±SD, with p-values from t-tests, or N (%), with p-values from Fisher's exact tests, unless stated otherwise.

Bold p-values are significant at $p < 0.05$

*p-Value from Kendall's Tau

Table 3 – Influence of factors on operating time.

Data reported as mean±SD, with p-values from t-tests, unless stated otherwise.

Bold p-values are significant at $p < 0.05$

*Pearson's r correlation coefficient

**p-Value from Jonckheere–Terpstra test

Table 1 – Demographics

	Statistic
Age (Years)	51 ± 15
Gender	
Male	79 (38.5%)
Female	126 (61.5%)
Ethnicity*	
White	183 (92.0%)
Other	16 (8.0%)
Grade of Surgeon	
Consultant	111 (54.1%)
Trainee	94 (45.9%)
Hiatus hernia	
Yes	38 (18.5%)
No	167 (81.5%)
ASA	
1	99 (48.3%)
2	94 (45.9%)
3	12 (5.9%)
Operating Time (Mins)	54 ± 14
Length of Stay	
0	185 (90.2%)
1	17 (8.3%)
2	1 (0.5%)
3	1 (0.5%)
7	1 (0.5%)

Data reported as mean±SD or N (%), as applicable

*Based on N=199

Table 2 – Associations with Length of Stay

	Length of Stay		p-Value
	0 Days	1+ Days	
Age (Years)	51 ± 14	55 ± 17	0.257
Operating time (Mins)	54 ± 13	55 ± 19	0.780
Gender			0.092
Male	75 (95%)	4 (5%)	
Female	110 (87%)	16 (13%)	
Ethnicity			1.000
White	164 (90%)	19 (10%)	
Other	15 (94%)	1 (6%)	
Grade of Surgeon			1.000
Consultant	100 (90%)	11 (10%)	
Trainee	85 (90%)	9 (10%)	
Hiatus Hernia			<0.001
Yes	27 (71%)	11 (29%)	
No	158 (95%)	9 (5%)	
ASA			0.001*
1	95 (96%)	4 (4%)	
2	82 (87%)	12 (13%)	
3	8 (67%)	4 (33%)	

Data reported as mean±SD, with p-values from t-tests, or N (%), with p-values from Fisher's exact tests, unless stated otherwise.

Bold p-values are significant at $p < 0.05$

*p-Value from Kendall's Tau

Table 3 – Influence of factors on operating time.

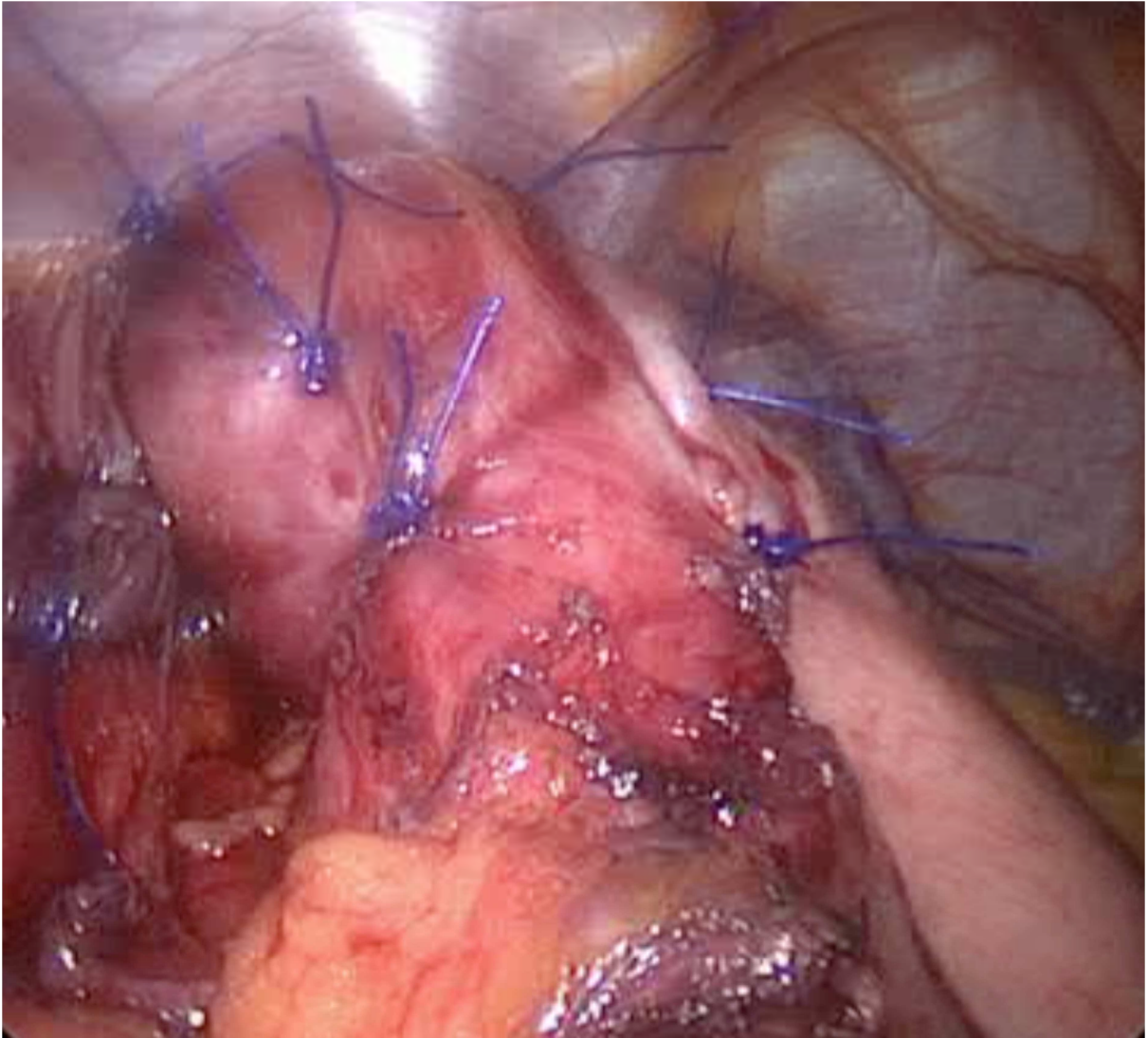
	Operating Time (Minutes)	p-Value
Age	$r=-0.04^*$	0.591*
Gender		0.484
Male	55 ± 13	
Female	53 ± 15	
Ethnicity		0.701
White	54 ± 14	
Other	55 ± 11	
Grade of Surgeon		<0.001
Consultant	45 ± 8	
Trainee	64 ± 12	
Hiatus Hernia		0.433
Yes	55 ± 17	
No	53 ± 13	
ASA		0.024**
1	56 ± 14	
2	53 ± 13	
3	48 ± 12	

Data reported as mean \pm SD, with p-values from t-tests, unless stated otherwise.

Bold p-values are significant at $p < 0.05$

*Pearson's r correlation coefficient

**p-Value from Jonckheere–Terpstra test



ACCEPTED

Highlights

Two hundred and five consecutive patients underwent laparoscopic fundoplication using an all 5 mm port technique with conversion to a 12 mm port only once (0.49 %).

In this unselected cohort, same day discharge was achieved in 89% of patients.

Hiatal hernia repair using mesh was performed without the need to convert to larger ports.

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