J Gastrointest Surg (2015) 19:1385–1390
DOI 10.1007/s11605-015-2807-2

ORIGINAL ARTICLE

Outcome for Asymptomatic Recurrence Following Laparoscopic Repair of Very Large Hiatus Hernia

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Received: 2 March 2015 / Accepted: 17 March 2015 / Published online: 31 March 2015

Abstract
Background Radiological follow-up following repair of large hiatus hernias have identified recurrence rates of 20–30 %, although most are small and asymptomatic. Whether patients will eventually develop clinical problems is uncertain. This study evaluated the outcome for individuals identified with an asymptomatic hiatus hernia following previous repair vs. asymptomatic controls.
Methods One hundred fifteen asymptomatic patients who had previously undergone sutured repair of a large hiatus hernia and then underwent barium meal X-ray 6–60 months after surgery within a clinical trial were identified and divided into two cohorts: with (n=41) vs. without (n=74) an asymptomatic hernia. Heartburn, dysphagia, and satisfaction with surgery were assessed prospectively using a standardized questionnaire applying analogue scales. Consumption of antisecretory medication and revision surgery were also determined. To determine the natural history of asymptomatic recurrent hiatus hernia, outcomes for the two groups were compared at 1 and 5 years and at most recent (late) follow-up.
Results Outcomes were available at 1 year for 98.2 % and 5 years or the latest follow-up (range 6–237 months) for 100 %. Heartburn and dysphagia scores were low and satisfaction scores high in both groups at all follow-up points, but heartburn scores and medication use were higher in the recurrent hernia group. At late follow-up, 94.6 % of the recurrent hernia group vs. 98.5 % without a hernia regarded their original decision for surgery to be correct. Two patients in recurrent hernia group underwent revision surgery.
Conclusions Patients with an initially asymptomatic recurrent hiatus hernia are more likely to report heartburn and use antisecretory medication at later follow-up than controls. However, overall clinical outcomes remain good, with high satisfaction and low surgical revision rates. Additional interventions to reduce the risk of recurrence might not be warranted.

Keywords Hiatus hernia · Laparoscopic repair · Barium meal X-ray

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Introduction

Laparoscopic approaches to fundoplication and repair of hiatus hernia were developed in the early 1990s,[1,2] and safety, efficacy, and durability are well documented.[3,4] However, experience with revisional antireflux surgery suggests that recurrent hiatus hernia is the most frequent indication for revision surgery, accounting for approximately 50 % of all revision operations.[5] Recurrent hiatus hernia after antireflux surgery has also been reported to occur more frequently following repair of very large hiatus hernias,[6] and in patients who have undergone repair of very large hernias, radiological follow-up studies have consistently identified radiological recurrences in

20 to 30 % of patients at medium to longer term follow-up.[7–13] However, the majority of recurrent hernias are small and appear to be asymptomatic, suggesting that for many patients, recurrence is a "radiological" diagnosis, and might not be a clinical problem. The natural history of asymptomatic recurrent hiatus hernias, however, is unclear, and follow-up studies which address this issue are few and of low quality. The question that needs to be addressed is whether patients with an asymptomatic "radiological" hiatus hernia, identified following laparoscopic repair of a very large hiatus hernia, will eventually develop symptoms which impact on quality of life and require surgical revision.

Some surgeons believe that if patients are followed for long enough, then these small asymptomatic hernias will inevitably become symptomatic, and this view leads to the belief that they indicate failure of the original repair. If this belief is valid, then it makes sense to prioritize achieving a durable anatomical repair when repairing a very large hiatus hernia. This might require mesh repair of the esophageal hiatus or a Collis procedure to "lengthen" the esophagus, and some surgeons have more recently advocated a lateral releasing incision in the left hemidiaphragm.[14] However, mesh placement at the esophageal hiatus can be followed by problems, including erosion of mesh into the esophagus, and the presence of mesh at the hiatus increases the difficulty of subsequent revision surgery.[15] Esophageal lengthening procedures can also be followed by serious complications, and the functional outcomes have been questioned.[16]

Knowledge about the longer term outcome in individuals with an asymptomatic "radiological" recurrence after hiatus hernia repair is critical to informing the debate about how to best repair hiatus hernias. If the risk of poor outcomes is high, then primary mesh repair or esophageal lengthening might be considered, whereas if the risk of problems is low, then the risks associated with mesh or esophageal lengthening might be excessive.

To address this question, we identified a group of asymptomatic patients who had previously undergone repair of a very large hiatus hernia and subsequently were investigated with a barium meal X-ray while symptom free as part of a clinical trial follow-up protocol. From this cohort, groups of patients with vs. without an asymptomatic hiatus hernia were identified, and their outcomes were compared to determine longer term clinical outcomes.

Methods

Patients who underwent laparoscopic repair of a very large hiatus hernia (>50 % of stomach contained in the hernia) and then subsequently had a postoperative radiological contrast X-ray (barium meal) as part of routine follow-up within a clinical trial were identified from a prospective database. The database included surgery performed at Flinders Medical Centre, Royal Adelaide Hospital, and associated private hospitals in Adelaide, South Australia. Patients were identified from within a larger cohort that underwent surgery between September 1991 and December 2011. All patients included in this study were symptom free at the time of the barium meal X-ray, and patients who underwent a barium meal X-ray to investigate symptoms (not part of a clinical trial assessment protocol) were excluded from this study.

All patients had originally participated in one of three previously reported clinical studies.[13,16,17] In these three studies, barium meal X-ray had been used for objective follow-up and determination of anatomy at a predetermined time point following surgery, irrespective of whether or not symptoms were present. The first study was a prospective cohort study which evaluated initial experience with laparoscopic Nissen fundoplication (including some individuals with a large hiatus hernia) between September 1991 and February 1994.[17] Only the large hiatus hernia cohort was included in the current study. The second study was also a prospective cohort study which evaluated barium meal X-ray outcomes following laparoscopic repair of large hiatus hernia between March 1994 and May 2001.[13] The third study was a prospective randomized trial of sutured vs. mesh repair of very large hiatus hernias, and it enrolled patients from February 2006 to September 2012.[18] In each of these three studies, barium meal X-rays were performed irrespective of symptoms at either 6 months or 5 years following the original surgery to assess postsurgical anatomy.

For the current study, only patients who were symptom free at the time they underwent barium meal X-ray were included. All patients from the three original studies who had symptoms at the time of the barium meal X-ray (all symptom scores >0; see below) were excluded. Patients were also excluded if they had undergone a surgical revision procedure prior to the barium meal X-ray, had undergone mesh repair of the hiatus hernia within the randomized trial (study 3), or had undergone surgery in another institution within the randomized trial (i.e., not within the Adelaide surgical cohort). Hence, all patients included in the analysis had undergone surgery for a very large hiatus hernia (>50 % of the stomach in the mediastinum at the original procedure) using sutures and were symptom free at the time of the radiological study—i.e., no symptoms of recurrent reflux, no dysphagia, no chest pain, and no other symptoms reported.

For comparison and analysis, the study cohort was divided into two groups based on the outcome of the barium meal X-ray: asymptomatic patients with a radiological recurrent hiatus hernia of any size vs. asymptomatic patients who had no evidence of a hiatus hernia at the time of barium meal X-ray. A recurrent hiatus hernia was determined to be present if any portion of the fundoplication or stomach was demonstrated to be located above the level of the diaphragm at X-ray.

The technique for the original laparoscopic repair of the very large hiatus hernias was standardized for the patients included in this study and has been described in detail previously.[19] All procedures entailed dissection and reduction of the hernia sac and contents into the abdomen, posterior hiatal dissection, hiatal repair using interrupted 2/0 monofilament nonabsorbable sutures, and then a partial or Nissen fundoplication, with the type of fundoplication at the discretion of the operating surgeon.

All patients were followed prospectively following surgery using a clinical follow-up protocol common to all three of the original studies. This applied a previously described follow-up questionnaire which was administered yearly by a research nurse.[20] Patients were asked questions about symptoms of heartburn, postoperative dysphagia for liquids and solids, and overall satisfaction with the outcome following surgery. These outcomes were assessed using 0–10 analogue scales. For heartburn and dysphagia, 0 indicated no symptoms and 10 indicated severe symptoms. For satisfaction, the scores were reversed so that 0 indicated dissatisfied and 10 highly satisfied. Based on previously reported outcome studies using these symptom scales, the scores were also clustered into four groups: 0=no symptoms, 1–3=minor symptoms which did not interfere with quality of life, 4–6=moderate symptoms, and 7–10=severe symptoms.[20] For the satisfaction score, a score of 7–10 indicated a high level of satisfaction with the overall outcome, 4–6 moderate satisfaction, and 0–3 a low level of satisfaction. Patients were also asked if they thought they had made the correct decision to undergo their original surgery. Consumption of antisecretory medication, as well as other clinical information, including details of the original and any revision operations, was also collected and analyzed.

As the current study sought to determine the natural history of patients with an asymptomatic hiatus hernia, follow-up was determined to commence from the time that the barium meal X-ray was performed, not from the time of the original surgery. Clinical symptom scores and revision surgery outcome data were compared at 12-month follow-up, at 5 years, and at the most recent available (late) follow-up for patients who had developed vs. had not developed a recurrent hiatus hernia. Statistical analysis was performed using SPSS version 16.0 (SPSS Inc, Chicago, IL). Continuous nonparametric variables were expressed as mean (standard deviation (SD)) and compared using the two-tailed Mann–Whitney *U* test. Fisher's exact test was used to determine the significance of 2×2 contingency tables and the chi-squared test for larger contingency tables. Differences were considered to be significant if $P<0.05$. Follow-up of the patients in these trials, as well as the original protocols was approved by the Human Research Ethics Committees of the participating hospitals.

Results

From January 1991 to December 2011, 2281 patients underwent laparoscopic fundoplication and/or repair of a hiatus hernia in our hospitals. Five hundred thirty five had a very large hiatus hernia, and from these, a subgroup of 115 individuals who met the inclusion criteria was identified. The remaining 420 patients who underwent repair of a very large hiatus hernia had not undergone a barium meal examination within a clinical trial or had either symptoms or had undergone previous revision surgery. Forty one (35.7 %) of the 115 individuals were asymptomatic and had a recurrent hiatus hernia identified by barium meal X-ray 6 months to 5 years after their original surgery (recurrent hernia group), and 74 (64.3 %) were asymptomatic and had undergone a barium meal X-ray which did not show a hiatus hernia (control group). The two groups were similar for gender (M/F 16:25 vs. 27:47; $P=0.843$) and age (62.41±13.04 vs. 66.73±10.71; $P=0.058$). All operations were completed laparoscopically, except one in the recurrent hernia group, which was converted to open surgery due to inability to fully reduce the hernia early in the series.

Clinical follow-up data was available at 12 months for 113 (98.2 %) patients, with no follow-up data available for two (1.8 %) patients who were lost to follow-up at this time point (one in each group). Follow-up data was available for all (100 %) eligible patients at 5 years or at the latest follow-up point, and no patients were lost to follow-up at these time points. At 5-year follow-up, clinical symptom scores were available for 71 patients, 39 had undergone surgery less than 5 years earlier (and hence excluded from 5-year follow-up analysis), and 5 had died from causes unrelated to their original surgery (2 in the recurrent hernia group and 3 in the group without recurrence). For the late follow-up, patients were followed for a mean 74.2 months (range 6–237 months) and clinical symptom scores were available for 102 patients, and 13 died from unrelated causes during follow-up (4 in the recurrent hernia group and 9 in the group without recurrence).

Symptom outcomes are summarized in Table 1. Heartburn scores were low in both groups at all follow-up points but were significantly higher in the recurrent hernia group at all follow-up points. Proton pump inhibitor use was also significantly higher in the recurrent hernia group at 12 months and the latest follow-up points. The dysphagia score for liquids was higher in the recurrent hernia group at 12-month follow-up but not at 5 years or the latest follow-up. The dysphagia score for solids was also higher in the recurrent hernia group at 12 months and 5-year follow-up but not at the latest follow-up point. Satisfaction scores were significantly lower in the recurrent hernia group at 12 months and at the latest follow-up, although the mean scores were high in both groups at all follow-up points.

Table 1 Clinical symptom outcomes at 1, 5 years, and the latest follow-up time points

	1 Year follow-up			5-Year follow-up			Latest follow-up		
	RHH	noRHH	p	RHH	noRHH	p	RHH	noRHH	p
n	40	73		22	49		37	65	
Demographics									
Gender (M/F)	15/25	26/47	0.841	11/11	17/32	0.295	15/22	22/43	0.527
Age at follow-up	66.05 (12.92)	70.29 (10.44)	0.061	65.09 (14.24)	74.37 (9.52)	0.002*	73.62 (10.30)	75.05 (10.41)	0.506
Heartburn									
Score	2.03 (3.03)	0.53 (1.63)	0.001*	1.73 (2.16)	0.55 (1.73)	0.002*	1.65 (2.52)	0.78 (1.96)	0.016*
0/1–3	22/9 77.5 %	61/7 93.2 %	0.033*	11/6 77.3 %	42/4 93.9 %	0.097	21/8 78.4 %	52/7 90.8 %	0.132
4–6/7–10	4/5 22.5 %	4/1 6.8 %		5/0 22.7 %	1/2 6.1 %		5/3 21.6 %	3/3 9.2 %	
Dysphagia									
Liquids score	0.83 (1.55)	0.15 (0.59)	0.002*	0.86 (1.88)	0.33 (1.09)	0.144	0.57 (1.21)	0.51 (1.48)	0.249
0/1–3	29/6 87.5 %	68/5 100 %	0.005*	17/2 86.4 %	42/4 93.9 %	0.365	28/7 94.6 %	56/5 93.8 %	1.000
4–6/7–10	5/0 12.5 %	0/0		3/0 13.6 %	1/2 6.1 %		2/0 5.4 %	2/2 6.2 %	
Solids score	1.95 (2.58)	0.93 (1.90)	0.013*	3.14 (3.69)	0.71 (1.83)	0.001*	2.08 (2.79)	1.28 (2.52)	0.105
0/1–3	20/10 75 %	53/14 91.8 %	0.022*	11/1 54.5 %	41/3 89.8 %	0.002*	21/6 73.0 %	47/8 84.6 %	0.196
4–6/7–10	7/3 25 %	3/3 8.2 %		6/4 45.5 %	4/1 10.2 %		6/4 27.0 %	5/5 15.4 %	
Satisfaction									
Satisfaction score	7.95 (2.25)	9.51 (1.40)	0.000*	8.64 (1.79)	9.31 (1.57)	0.078	8.08 (2.63)	9.03 (2.14)	0.010*
0–3/4–6	3/6 22.5 %	1/2 4.1 %	0.004*	1/1 9.1 %	1/0 2.0 %	0.225	3/5 21.6 %	3/1 6.2 %	0.027*
7–10	31 77.5 %	70 95.9 %		20 90.9 %	48 98.0 %		29 78.4 %	61 93.8 %	
PPI use (%)	19 (47.5)	13 (17.8)	0.002*	10 (45.5)	11 (22.4)	0.090	18 (48.6)	18 (27.7)	0.052
Diet normal (%)	31 (77.5)	68 (93.2)	0.033*	18 (81.8)	42 (85.7)	0.729	31 (83.8)	61 (93.8)	0.163
Original decision correct	40 (100)	72 (98.6)	1.000	19 (86.4)	48 (98.0)	0.085	35 (94.6)	64 (98.5)	0.297

All figures expresses as mean (standard deviation) or number (%)

PPI proton pump inhibitor, *RHH* recurrent hiatus hernia

*$P<0.05$

A normal diet was less likely to be consumed at 12 months in the recurrent hernia group, but diet was similar for the two groups at 5 years and the latest follow-up points.

When asked whether the original decision to have surgery was correct, most patients indicated "yes." There were no significant differences between the groups for this question, and when this question was used to determine the clinical success rate at the latest follow-up, success rates of 94.6 vs. 98.5 % were identified.

During the full follow-up period, two (4.9 %) patients in recurrent hernia group underwent revision surgery for reherniation, with three operations undertaken in these two patients. One patient underwent revision at 31- and 72-month follow-up. The other underwent revision at 60-month follow-up. Hence only 2 of 115 patients undergoing a suture repair of a large hiatus hernia required revision surgery for reherniation (1.7 %). A further patient underwent esophagectomy at 22-month follow-up for an early stage (T1) esophageal cancer in Barrett's esophagus.

Discussion

One of the most frequently cited reasons for failure following antireflux surgery and hiatal hernia surgery is recurrent hiatus hernia.[21] Routine radiological follow-up studies have shown apparently high failure rates, with barium meal radiology assessment studies consistently showing recurrence rates of 20 to 30 % after laparoscopic repair of large hiatal hernias.[7–13] In a review of 17 published series, which included 1167 laparoscopic revision fundoplications, Van Beek et al. demonstrated that recurrent hiatus hernia accounted for failure in nearly half of the patients who underwent revision.[5]

The issue of asymptomatic recurrence following repair of hiatus hernia is controversial, and there is disagreement about the clinical significance of this problem, whether or not it should be fixed by further surgery and whether additional steps such as mesh repair, esophageal lengthening, or a lateral releasing incision in the left hemidiaphragm should be taken at the primary operation to prevent this problem from occurring. Some surgeons believe that the natural history of a recurrent hiatus hernia is similar to the original hiatal hernia and that it

will enlarge with time and result in significant symptoms.[22] In contrast, others advocate conservative management and point out that the natural history and risk of progressing to a complication is unknown. Despite high recurrence rates reported in some studies, it appears that only a small percentage (less than 5 %) of the recurrences progress to reoperation.[8,12,13,23]

Few previous studies have specifically addressed the outcome in patients with an asymptomatic recurrent hiatus hernia, and most of these studies have focused on general outcomes following surgery for large hiatus hernia,[7,24–26] rather than the specific outcome in patients with asymptomatic recurrences. These reports do, however, suggest that most asymptomatic recurrences might not be clinically relevant, as the initial size of the recurrent hernia is generally small, most do not increase in size over time, few are symptomatic, and recurrences seem unlikely to progress to serious complications. These studies generally conclude that most hernia recurrences follow a benign course and the need for reoperation is uncommon. However, previous studies have been limited by the heterogeneity of the patient cohorts and a lack of focus on the recurrence question.

By pooling patient cohorts from three previous studies,[13,17,18] we were able to identify a group of patients with an asymptomatic recurrent hiatus hernia after previous repair of a very large hiatus hernia and a matched control group without a hernia who underwent the same radiological assessment and follow-up protocol. This has provided a unique opportunity to determine the longer term outcome for patients with an asymptomatic recurrence following sutured repair of a large hiatus hernia. Strengths of our data set include the completeness of follow-up, with no patients lost to follow-up at the 5 year and later follow-up points, as well as standardization of the clinical outcome assessment. However, follow-up in our study was limited to clinical outcomes, and as sequential barium meal X-rays were not undertaken, whether a recurrent hernia increases in size over time was not addressed. Nevertheless, the clinical outcomes do provide important information about whether patients are likely to progress from an asymptomatic recurrent hiatus hernia to significant symptoms or further revision surgery, and this information should inform debate about how to perform primary surgery for hiatus hernia. In this context, it is important to consider that none of the patients included in our study underwent mesh repair of their hiatus hernia or an esophageal lengthening procedure, and yet, the rate of revisional surgery remained low at less than 2 %.

The data from our study has shown more heartburn and reflux symptoms and greater use of proton pump inhibitor medication in the recurrent hernia group. This outcome was similar to that reported by White et al.[7] who identified 60 vs. 14 % rates of heartburn at 10-year follow-up in a small cohort of 31 patients with vs. without a recurrent hernia. This suggests that the significance of a small recurrent hiatus hernia is more likely to be recurrent reflux issues, rather than other symptoms. This is plausible as a small hernia often entails slippage of the gastroesophageal junction into the chest, resulting in a "slipped fundoplication" but is not big enough to lead to other problems. In this context, proton pump inhibitors appeared to provide effective relief of reflux symptoms, with no patient requiring revisional surgery for reflux in our study.

Dysphagia was also more common at earlier follow-up points but not at later follow-up. This was not associated with significant difficulties with eating in most individuals, as most were able to eat a normal range of food. Nevertheless, dysphagia might have contributed to a poorer outcome in a few patients. Consistent with this, the satisfaction scores were high overall, but the mean satisfaction score was less in recurrent hernia group. However, 94.6 and 98.5 % of patients in each group considered that they had made the correct decision to undergo surgery, suggesting most remained well satisfied with their overall outcome.

If the risk of recurrent hernia is to be reduced, then two possible approaches should be considered: an esophageal lengthening procedure or mesh reinforcement of the hiatus. However, these approaches remain controversial, with different opinions in different parts of the world due to different perceptions of the risks associated with these procedures.[15,16] The risks of esophageal lengthening or mesh need to be balanced against the risk of problems arising following repair using only sutures. Esophageal lengthening adds complexity to the surgical repair and is accompanied by a risk of gastrointestinal leakage and poor functional results.[16] Complications associated with the use of mesh to repair the hiatus include mesh erosion into the esophageal lumen, stenosis at the hiatus, and esophageal obstruction.[15,27] Revisional surgery following mesh placement is also difficult, and mesh erosion into the esophagus will often lead to esophagectomy.[15] In addition, two randomized controlled trials of mesh vs. sutured hiatal repair of large hiatus hernias have failed to show a reduction in hernia recurrence rates following mesh repair.[18,28] While the data from our current study shows that some problems do arise in a subgroup of patients during follow-up of asymptomatic recurrent hiatus hernias, the risk of significant problems that require intervention beyond use of proton pump inhibitor medication appears to remain low. Our study actually suggests a relatively low overall risk (4.9 %) of progressing to revision surgery at late follow-up.

The current study has shown that patients diagnosed initially with an asymptomatic recurrent hiatus hernia after laparoscopic repair of a very large hiatus hernia are at later follow-up more likely to report symptoms of heartburn and dysphagia, are more likely to consume proton pump inhibitor medication, and report lower satisfaction scores than matched controls without a recurrent hernia. However, the clinical outcomes in most of the patients with a recurrent hernia are

actually still very good, with a very high rate of satisfaction with the surgical outcome despite the recurrent hernia, and the rate of surgical revision in these patients is also low. Additional interventions to reduce the risk of recurrence, including mesh or esophageal lengthening might not be warranted.

Acknowledgments The authors are grateful to their colleagues from the Royal Adelaide Hospital and Flinders Medical Centre who contributed clinical cases to the database and also to Ms Lorelle Smith, Ms Marian Martin, Ms Lorraine Sheehan-Hennessy, and Ms Nicky Carney who managed the database and clinical follow-up.

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