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Durability of giant hiatus hernia repair in 455 patients over 20 years

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ABSTRACT

INTRODUCTION The surgical management of symptomatic giant hiatus hernia (GHH) aims to improve quality of life (QoL) and reduce the risk of life threatening complications. Previous reports are predominantly those with small sample sizes and short follow-up periods. The present study sought to assess a large cohort of patients for recurrence and QoL over a longer time period.

METHODS This was a follow-up study of a prospectively collected database of 455 consecutive patients. Primary repair of GHH was evaluated by endoscopy/barium meal for recurrence and a standardised symptom questionnaire for QoL. Recurrence was assessed for size, elapsed time, oesophagitis and symptoms.

RESULTS Objective and subjective review was achieved in 91.9% and 68.6% of patients. The median age was 69 years (range: 15–93 years) and 64% were female. Laparoscopic repair was completed in 95% (mesh in 6% and Collis gastroplasty in 7%). The 30-day mortality rate was 0.9%. The proportion of patients alive at five and ten years were 90% and 75% respectively. Postoperative QoL scores improved from a mean of 95 to 111 ($p<0.01$) and were stable over time (112 at 10 years).

The overall recurrence rate was 35.6% (149/418) at 42 months; this was 11.5% (48/418) for hernias >2cm and 24.2% (101/418) for <2cm. The rate of new recurrence at 0–1 years was 13.7% (>2cm = 3.4%, <2cm = 10.3%), at 1–5 years it was 30.8% (>2cm = 9.5%, <2cm = 21.3%), at 5–10 years it was 40.1% (>2cm = 13.8%, <2cm = 26.3%) and at over 10 years it was 50.0% (>2cm = 25.0%, <2cm = 25.0%). Recurrence was associated with oesophagitis but not decreased QoL. Revision surgery was required in 4.8% of cases (14.8% with recurrence). There were no interval major GHH complications.

CONCLUSIONS Surgery has provided sustained QoL improvements irrespective of recurrence. Recurrence occurred progressively over ten years and may predispose to oesophagitis.

KEYWORDS

Hiatal hernia – Gastro-oesophageal reflux – Laparoscopy – Fundoplication – Quality of life – Patient outcome assessment

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It is generally accepted in surgical circles that symptomatic giant hiatus hernias (GHHs) should undergo elective surgical repair given the risks of non-operative management.[1–3] A recent (and large) population-based observational study identified a 16.4% risk of death when hospitalised symptomatic patients are treated conservatively.[2] Patients are often elderly and frail,[4] and so a balance of surgical risk and life expectancy is required when considering surgical repair. There is, however, ongoing uncertainty, in part owing to the lack of long-term follow-up studies in regard to the natural history of the condition and the durability of repair and symptom improvement.

Ideally, the surgical repair of a GHH should be associated with a low morbidity and low risk of recurrence, favourable postoperative quality of life (QoL) indices, low reoperation rates and prevention of interval hiatus hernia complications. Recurrence rates of up to 66% have been reported.[5,6] As a result, numerous techniques have evolved with the aim of reducing recurrence rates. These techniques have included mesh hiatal repair[7] and Collis gastroplasty.[8,9] Reported recurrence rates have been variable and depend on the definition used[5,6] with some series excluding recurrence less than 2cm.[5,7,10]

QoL has been shown to be improved following repair.[10] This improvement is not only in gastrointestinal symptoms but also impacts on general wellbeing and cardiorespiratory symptoms.[11,12] There are, however, limited data on the durability of improvement and the prevention of

interval hiatus hernia complications.[8,13] The effect of recurrence on QoL has not been extensively investigated but recent studies suggest recurrence does not reduce symptomatic outcome.[5,14] The aim of our study was to assess the objective recurrence, QoL and oesophagitis over a long postoperative term in patients undergoing primary repair of GHH.

Methods

A prospectively populated database was maintained. The database was approved serially by an institutional ethics review board and consisted of consecutive patients referred from within the state of New South Wales, Australia, undergoing GHH repair in a single surgical practice between January 1991 and February 2012. Surgery was performed primarily by the senior author (GLF) or under his supervision. For a period of eight months in 2007 during the senior surgeon's leave of absence, locum surgeons performed operations at the same three tertiary referral hospitals and according to their usual practice. GHH was defined as type III or IV hiatus hernia with more than 50% of the stomach in the mediastinum or type II hiatus hernia with more than 30%,[1,10] based on preoperative barium meal and/or operative findings. Patients who had undergone previous surgery for GHH were excluded so that only primary repair was evaluated.

Surgical technique

Technical details have been published recently.[15,16] In brief, patients underwent complete removal of the hernia sac from the mediastinum and crural attachments. The oesophagus was mobilised in the mediastinum for sufficient length to allow tension free positioning of the gastro-oesophageal junction to a length of 2cm in the abdomen. The pillars of the crura were sutured deeply, including the central tendinous core (between 1 and 4 sutures being required), posteriorly and also frequently anteriorly. Calibration of the hiatus and the fundoplication was performed with a 52Fr bougie in female and a 56Fr bougie in male patients.

A Collis gastroplasty[17] was used for a period during an unpublished randomised study.[18] Mesh was largely used during the locum surgical practice period. Fundoplication was performed routinely, with its nature evolving. This was predominantly 360° and similar to that described by DeMeester *et al*,[19] and Rossetti and Hell.[20] After 2007, however, it incorporated an oesophagopexy and cardiopexy to the right crus as a 'composite repair'.

Review

Patient review was undertaken at six weeks and three months following surgery. Patients were asked subsequently to participate in follow-up consultations on a two-yearly basis. Attempts were made to contact all patients in June 2012 (census date) and a standardised QoL questionnaire was mailed to patients. This incorporated a Gastrointestinal Quality of Life Index (GIQLI) test after 1995,[21] gastro-oesophageal reflux disease assessment by modified Visick score[22] and DeMeester symptom profile,[23] a validated dysphagia score,[24] laryngopharyngeal reflux and overall satisfaction scores. The QoL questionnaire was self-administered or conducted by trained medical students or clinic staff. Objective follow-up review for recurrence was planned within one year of surgery and at census, often additionally being undertaken in the interim. Endoscopy was performed predominantly in the unit but for remote patients, regional endoscopy or a barium meal was undertaken.

Data management

The variables reviewed were age, operation date, laparoscopic or open surgery, fundoplication method, time to death, QoL, endoscopy and barium studies. Missing data points were obtained where possible from computerised patient records and local doctors by clinic staff, medical officers and medical students.

The primary outcomes assessed were objective recurrence of hiatus hernia and QoL. Recurrence of hiatus hernia was graded as total rate and size of >2cm or <2cm. Recurrence was also classified with respect to those hernias that had been identified by objective testing during the postoperative time periods 0–1, 1–5, 5–10 and >10 years. This was to enable comparison with previous published series[7,10] and to assess the patterns of recurrence. Recurrence was recorded at the date of objective tests. Barium images were reviewed by the unit radiologist if there was discordance in the reports. Individual patient QoL scores were averaged preoperatively and also within postoperative periods 0–1, 1–5, 5–10 and >10 years. Patients' results were censored at revision surgery. Presence of oesophagitis and Barrett's oesophagus were recorded from postoperative endoscopy.

Data were extracted to the software package STATISTICA version 8.0 (StatSoft, Tulsa, OK, US). QoL comparisons were analysed using Student's t-test for those patients who had paired data available and also using the Mann–Whitney U test for all unpaired data. Non-parametric data were analysed with Kruskal–Wallis analysis of variance and Student's t-tests. A p-value of <0.05 was considered statistically significant.

Results

GHH repair was performed in 475 patients. Primary repair was undertaken in 455 patients and they are the subject of this report. The median age was 69 years (range: 15–93 years) and 64% (n=292) were female.

Successful laparoscopic procedures were performed in 95% of patients. (Half of the open procedures had been performed during 1992–1996.) Composite fundoplication was used in 69% of patients, with DeMeester–Rossetti, Dor and Toupet techniques in 25%, 4% and 1% respectively. Mesh repair was undertaken in 27 patients (6%) and Collis gastroplasty in 33 patients (7%) as part of a randomised study, with no cases being performed for the inability to reduce the cardio-oesophageal junction into the abdomen. The mortality rate at 30 days was 0.9% (n=4, 3/4 undergoing surgery for acute strangulation). Survival data were

available for 98% (444/455 patients). The overall median follow-up duration was 32 months (range: 0–235 months). The overall survival rate was 90% at 5 years and 75% at 10 years with median survival being 192 months.

Recurrence

Anatomical follow-up was obtained in 418 patients (91.9%) and the median time to the most recent follow-up review was 13.2 months (range: 0–241 months). The recurrence rate at any postoperative time period was 35.6% (149/418), with a mean of 42 months following surgery (interquartile range: 6–60 months). Most recurrences were <2cm (101/149). The recurrence rate for larger hernias (>2cm) at any postoperative time period was 11.5% (48/418) while the recurrence rate for smaller hernias (<2cm) was 24.2% (101/418). A new diagnosis of recurrence (any size) continued to be identified from the first postoperative year to beyond ten years postoperatively (Table 1).

Revision

Revision operations were performed in 22 of the 149 patients with identifiable recurrence (14.8%) or 4.8% of the entire study population. No revision surgery was undertaken for strangulated recurrent hiatus hernia. These patients were predominantly those with >2cm recurrence (18 patients) and only four reoperations were performed when the recurrence was <2cm (all performed for significant symptoms attributable to recurrence). Reoperation occurred at a median of 23.3 months (range: 2 days – 90 months). Laparoscopic revision was undertaken in 12 patients. In those patients undergoing further objective testing after revision surgery, 39% had evidence of further recurrence (7/18: 3 following open and 4 following laparoscopic revision).

Oesophagitis and Barrett's oesophagus

Endoscopy was performed in 339 patients following surgery and 49 patients (14%) were found to have oesophagitis. Barrett's oesophagus was found in 94 patients (28% of those having endoscopy). Oesophagitis occurred in 29% (20/70) of patients with recurrence and in 11% (29/269) of those without (p=0.0004). The presence of oesophagitis was significantly different between the groups but it did not affect QoL scores.

Quality of life

At least one QoL questionnaire had been completed by 68.6% of patients following surgery (n=312). Overall postoperative QoL scores improved significantly. In paired analysis of the 136 patients having both pre and postoperative GIQLI tests, the preoperative mean score of 88 improved to 107 following surgery (mean improvement: 19, 95% confidence interval: 14–24, p<0.0001). In comparing unpaired data of individual QoL scores, postoperative improvement was identified for all parameters except the dysphagia score (Table 2). All scores remained stable beyond ten years postoperatively (Table 3). There was no difference in QoL scores in the presence of recurrence (Table 4).

Preoperative symptomatology on quality of life

Patients with the worst preoperative GIQLI score showed the greatest improvements in QoL scores after surgery. Those in the lowest preoperative GIQLI quartile showed a mean improvement of 67% and the second lowest quartile showed an improvement of 18%. Those in the second highest preoperative GIQLI quartile showed a mean improvement of 5% and the highest quartile showed a 5% worsening of GIQLI score.

Discussion

The patient group in this study was elderly and consistent with other series.[5,10,25] The longevity of our group was surprising, with 75% remaining alive at ten years. This may reflect the life expectancy increase in the Western world; at the average age of this group (69 years), the life expectancy is 16.0 years for men and 18.6 years for women.[26] It certainly demonstrates that hernia repair requires durability. Surgery appears to have been relatively safe in this series, with a low mortality, despite the elderly nature of the patient group and the low morbidity (8%) reported in an earlier report from our group.[16] The mortality rate at 30 days of 0.9% compares favourably with the natural history of symptomatic GHH, with a 16.4% mortality rate over 4 years in a study from 2009.[2]

Recurrence of hiatus hernia following surgery has been a consistent problem in many reports and has led to varied techniques of repair including the Collis gastroplasty, mesh hiatal repair and gastropexy procedures.[7,9,27] The overall

Table 1 Objective testing and recurrence rates stratified by time

	0–1 years	1–5 years	5–10 years	>10 years
Number having objective test*	321/455 (70.5%)	211/416 (50.7%)	80/299 (26.8%)	12/190 (12.6%)
Overall rate of new diagnosis of recurrence	13.7%	30.8%	40.1%	50.0%
Rate of new diagnosis of >2cm recurrence	3.4%	9.5%	13.8%	25.0%
Rate of new diagnosis of <2cm recurrence	10.3%	21.3%	26.3%	25.0%

*Denominator is the number of patients eligible for testing given that they had reached the respective follow-up period.

Table 2 Quality of life scores compared before and after surgery

Scoring test	Preoperative (*n*=147)			Postoperative (*n*=312)			*p*-value[a]	Change
	Median	Range	SD	Median	Range	SD		
GIQLI (0–144)[b]	95	28–133	23.0	111	33–144	23.0	**<0.01**	Improved
Symptoms	50	17–75	12.0	60	17–97	12.0	**<0.01**	Improved
Emotional	11	0–15	4.0	13	0–16	3.6	**<0.01**	Improved
Physical	15	0–26	6.4	17	0–28	6.2	**<0.01**	Improved
Social	13	2–16	3.6	14	0–33	3.5	**0.02**	Improved
Medical treatment	4	0–4	1.0	4	1–4	0.8	**<0.01**	Nil
Visick (0–4)[c]	3	0–4	1.0	2	0–4	0.9	**<0.01**	Improved
Dysphagia (0–45)[b]	37	6–45	11.1	39	0–45	9.4	0.18	Improved
DeMeester (0–12)[c]	8	0–12	3.0	4	0–12	4.2	**<0.01**	Improved
Laryngopharyngeal reflux (0–45)[c]	15	0–45	11.0	8	0–43	10.0	**<0.01**	Improved
Satisfaction (0–3)[b]	–	–	–	3	0–3	0.8	–	–

SD = standard deviation; GIQLI = Gastrointestinal Quality of Life Index
[a]Mann–Whitney U test; [b]Higher score reflects favourability; [c]Lower score reflects favourability

Table 3 Postoperative quality of life scores stratified by time

Scoring test	0–1 years (*n*=134, 29%)		1–5 years (*n*=109, 24%)		5–10 years (*n*=78, 17%)		>10 years (*n*=63, 14%)		*p*-value[a]
	Median	Range	Median	Range	Median	Range	Median	Range	
GIQLI (0–144)[b]	111	47–141	108	33–144	112	42–144	112	41–138	0.32
Symptoms	59	27–75	59	25–97	61	24–76	61	17–76	0.31
Emotional	13	1–16	13	0–16	13	3–16	13	3–16	0.49
Physical	17	3–28	16	0–28	19	4–28	18	1–26	0.07
Social	14	3–16	14	0–33	14	4–16	14	2.5–16	0.71
Medical treatment	4	1–4	4	1–4	4	1–4	4	1–4	0.27
Visick (0–4)[c]	2	1–4	2	0–4	2	0–4	2	0–4	0.36
Dysphagia (0–45)[b]	37	8–45	39	10–45	39	0–45	41	16–45	0.3
DeMeester (0–12)[c]	4	0–48	5	0–24	4	0–12	5	0–10	1
Laryngopharyngeal reflux (0–45)[c]	9	0–36	9	0–43	7	0–39	6	0–37	0.96
Satisfaction (0–3)[b]	3	0–4	3	0–3	3	0–4	3	0–3	0.57

GIQLI = Gastrointestinal Quality of Life Index
[a]Kruskal–Wallis analysis of variance; [b]Higher score reflects favourability; [c]Lower score reflects favourability

recurrence rate identified in this study of 35.6% is similar to that found in another large Australian series by Aly *et al*, who reported a 30% rate at a median of 4 years.[25] The largest published series of GHH, by Luketich *et al*, found a 15.7% recurrence rate at a median of 25 months in objective testing of hernias that were >2cm (or 10% of the stomach).[10]

In our series, there was a recurrence rate of 11.5% for hernias of this size. There were higher rates of small recurrent hiatus hernias (<2cm), which may lead to oesophagitis and symptoms. Although these may be of symptomatic consequence, it would appear unlikely that these would lead to revision surgery over the next 10–15 years given that only 4 patients with recurrences of small hernias required reoperation. No patients suffered an interval serious hiatus hernia complication.

Recurrence appeared to occur consistently over the years; the rate of new recurrences may even be increasing.

Table 4 Postoperative quality of life scores compared with and without hernia recurrence

Scoring test	No recurrence (*n*=333)		Recurrence <2cm (*n*=35)		Recurrence >2cm (*n*=21)		*p*-value[a]
	Median	Range	Median	Range	Median	Range	
GIQLI (0–144)[b]	108	33–144	114	67–142	108	64–132	0.33
Symptoms	59	17–101	61	30–101	61	45–73	0.24
Emotional	13	0–16	13	4–16	11	3.5–16	0.69
Physical	17	0–101	20	6–101	15	2–26	0.06
Social	14	0–33	14	6–101	14	5–16	0.32
Medical treatment	4	1–4	4	2–4	4	1–4	0.61
Visick (0–4)[c]	2	0–4	2	0–4	2	0–4	0.64
Dysphagia (0–45)[b]	38	0–45	39	19–45	45	18–45	0.21
DeMeester (0–12)[c]	4	0–12	6	0–10	6	0–11	0.08
Laryngopharyngeal reflux (0–45)[c]	8	0–43	9	0–37	6	0–32	0.98
Satisfaction (0–3)[b]	3	0–3	3	0–3	2	0–3	0.20

GIQLI = Gastrointestinal Quality of Life Index
[a]Kruskal–Wallis analysis of variance; [b]Higher score reflects favourability; [c]Lower score reflects favourability

The potential risk of bias in the long term must be realised, however, as patients with recurrence may be more likely to present for follow-up review. Our study had only a small proportion of patients undergoing objective testing beyond ten years. This reflects that many of these patients have become increasingly elderly, unfit and unwilling to undertake tests (especially if not symptomatic) or have died. Postoperatively, as age increased, patients became more difficult to locate and contact.

This study did not systematically utilise mesh or Collis gastroplasty and recurrence rates largely reflect a standard non-mesh approach. These data would indicate that other techniques are not necessary,[28] especially considering a study by our group published in 2013 of 100 patients undergoing a composite repair alone (2% and 7% symptomatic and non-symptomatic recurrence rate respectively, at a mean follow-up of 574 days).[16] There is also concern with the rare but problematic complication of mesh erosion and high risk of resection when refashioning in the presence of previous mesh.[29] Short oesophagus was probably rare in this study owing to the lack of stricture cases and nearly 30 years of availability of potent acid suppression, largely eliminating the short oesophagus. The Collis operations were done in a trial situation and did not reflect inability to reduce the cardio-oesophageal junction into the abdomen so no 'real' cases were found in the 455 procedures.

Reoperation rates for recurrence were low at 5% and occurred predominantly in patients with recurrence of hernias greater than 2cm. It would therefore appear prudent to continue to survey patients with recurrent hiatus hernia by both symptomatic and objective study to detect enlarging recurrent hernias.

It was disappointing that 39% of patients undergoing repeat repair relapsed again. This is in contrast to another report where only 3 of 26 patients recurred following revision.[30] However, this low reported rate may reflect early follow-up and later objective review is likely to report a higher rate. Another series reported 5 of 52 patients relapsing after undergoing repair for recurrence although objective follow-up methods and results were not reported.[31] The relatively high rate we identified should be considered in decision making regarding revision surgery, which is more challenging technically, more likely to be open and potentially more risky.[30] Importantly, reoperation was not necessary in this cohort for acute complications of GHH, which is one of the most important indications for primary surgery.

The symptomatic effect of recurrent hiatus hernia after repair is consistent with other large series where QoL appeared not to be affected following recurrence.[5,10,14] The results were not statistically significant, however, casting some uncertainty on this finding. Our study showed oesophagitis was significantly more common after recurrence. In addition, the protocol of undertaking postoperative endoscopy, which assessed recurrence and oesophagitis, interestingly identified a 28% rate of Barrett's oesophagus. Aly *et al* also identified a significant rate of Barrett's epithelium of 13% on preoperative endoscopy.[25] While preoperative endoscopy was performed too infrequently to allow comparison with postoperative endoscopy, these statistics do reflect the longstanding nature of reflux in some patients with GHH. It would seem prudent to perform postoperative endoscopy to detect a significant rate of Barrett's oesophagus, especially given the availability of effective endoscopic treatments of dysplasia, and oesophagitis manageable by medical therapy. The presence of oesophagitis did not influence QoL, possibly reflecting insensitivity of the oesophagus or the QoL measure.

Surgery led to a marked improvement in QoL. This was seen in GIQLI scores, reflux scores and laryngopharyngeal reflux scores. The effect extended beyond ten years. This has also been found in earlier studies.[5]

The longer-term objective data in our study were limited. Additionally, the postoperative objective and subjective tests were undertaken variably and sometimes inconsistently. These factors reduce the strength of our conclusions. The database did not contain morbidity data so this could not be reported. Nevertheless, a 2013 publication from our group prospectively analysing a recent cohort found an 8% rate of perioperative complications.[16]

Conclusions

There was an unexpected longevity in this cohort. Surgical repair of GHH provided a sustained improvement in QoL despite recurrence. There were no severe hiatus hernia related events following surgery, thereby reducing risks associated with GHH. Recurrence was associated significantly with an increased risk of oesophagitis. There was a high rate of Barrett's oesophagus, indicating that surveillance is important. More severely symptomatic patients benefit most from surgery. Mesh repair has not been required for adequate prolonged QoL improvement and short oesophagus appears infrequent.

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