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ORIGINAL ARTICLE

Crura augmentation with Bio-A® mesh for laparoscopic repair of hiatal hernia: single-institution experience with 100 consecutive patients

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Abstract
Background The potential utility of both non-absorbable and absorbable meshes to reinforce the esophageal hiatus and prevent recurrent hernia has been investigated in observational studies and a few randomized clinical trials. Use of absorbable mesh has been associated with lesser side-effects, but the long-term safety and effectiveness are still debated. This rather scanty clinical evidence is due to heterogeneity and bias regarding the type of mesh and operation used, the modalities of follow-up, and the reporting of objective results.
Objectives The aim of the study was to assess safety, quality of life, and recurrence-free probability after laparoscopic repair of hiatal hernia reinforced with a synthetic absorbable mesh.
Methods Observational, retrospective, single-center cohort study. All patients with hiatal hernia who underwent laparoscopic crura repair using a biosynthetic mesh (Gore Bio A® tissue reinforcement, Flagstaff, AZ) were included. Pre- and post-operative symptoms were assessed with the GERD-HRQL questionnaire. Objective follow-up consisted of upper gastrointestinal endoscopy and barium swallow study.
Results From September 2011 to March 2016, a total of 100 patients underwent hiatal hernia repair using a Bio-A® mesh. All surgical procedures were completed laparoscopically. Postoperative morbidity rate was 10%. All patients had a minimum follow-up of 6 months, and the median follow-up was 30 (IQR = 22) months. No mesh-related complications occurred. The incidence of recurrent hernia ≥2 cm was 9%, and eight of the nine patients had a preoperative type III hernia. The median GERD-HRQL score was significantly reduced after operation ($p < 0.001$). The recurrence-free probability at 1 and 5 years was, respectively, 0.99 (CI 0.97–1.00) and 0.84 (CI 0.74–0.97), and no reoperation was required. No association was found between age, BMI, hernia size, previously failed surgical repairs and hernia recurrence.
Conclusions The use of a synthetic absorbable mesh to reinforce the esophageal hiatus is safe and appears to be effective and durable over a medium-term follow-up.

Keywords Hiatus hernia · Laparoscopic hiatus hernia repair · Recurrent hernia · Fundoplication

Introduction

Over the past 25 years, laparoscopic hiatal hernia repair has replaced the traditional laparotomic and thoracotomic approach, and has resulted in a reduction of length of hospital stay and morbility, and increased patients' acceptance [1]. Nowadays, elective surgery is recommended even in asymptomatic patients with large paraesophageal hernia because of the potential to develop mechanical complications, such as gastric volvulus, severe postprandial discomfort, exertional dyspnea, and/or recurrent anemia requiring blood transfusions [2]. Laparoscopic reduction of the herniated stomach, combined with suture cruroplasty and Toupet or Nissen fundoplication, is the current gold standard of treatment, but the high propensity for anatomical and clinical recurrences remains

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problematic [3, 4]. For this reason, there has been an increasing interest in the use of prosthetic mesh to reinforce the esophageal hiatus [5, 6]. The use of non-absorbable mesh has been questioned mostly due to concerns about the risk of severe complications leading to esophagectomy in some patients [7]. The aim of this study was to report the medium-term results of our first 100 patients who underwent laparoscopic hiatal hernia repair with the use of a new absorbable synthetic mesh.

Methods

Study design

This is an observational, retrospective, single-center cohort study on consecutive patients with hiatal hernia. Four types of hiatal hernia were recognized according to a comprehensive classification system [8]. Crura reinforcement with Bio-A® mesh and Toupet fundoplication were routinely performed. Patients were followed over time to evaluate safety, quality of life, and recurrence-free probability. Hiatal hernia recurrence was defined as the maximum vertical height of stomach being at least 2 cm above the diaphragmatic impression at endoscopy or barium swallow. The study was approved by the Internal Review Board (protocol no. LHH 7.3.2016). Written informed consent was obtained from all patients.

All patients underwent a standard preoperative assessment including medical history, GERD-HRQL questionnaire, physical examination, blood test analysis, EKG, chest X-ray, barium swallow study, and upper gastrointestinal endoscopy with biopsies. In selected patients, esophageal manometry, CT scan of chest and abdomen, cardiac magnetic resonance and/or cardiopulmonary exercise test were also performed [9]. A chest film and a gastrographin swallow study were performed on postoperative day one to check the correct placement of the mesh and the position of the gastroesophageal junction. A soft diet was then allowed and thereafter patients were discharged home.

Outpatient follow-up visits were scheduled at 1, 3, 6, and 12 months after operation, and then yearly. The GERD-HRQL questionnaire, a validated assessment tool [10], was administered 3 months after the discharge and then yearly. Either a barium swallow study or an upper gastrointestinal endoscopy were performed between 6 and 12 months after surgery, and were subsequently repeated every 1–2 years and at any time the patient complained of symptoms. For the purpose of the study, the latest follow-up data available (October 2016) were used for analysis.

Surgical technique

Five trocars were used for the laparoscopic approach. The first step of the operation consisted of reduction of the herniated stomach, excision of the hernia sac, and mobilization of at least 3 cm of tension-free intra-abdominal esophagus. Care was taken to preserve both vagal nerves. Primary posterior cruroplasty was routinely performed using interrupted, non-absorbable sutures, and keeping the pneumoperitoneum at 8 mmHg to reduce tension and assist in the recruitment of the left crus. If needed, the left crus was plicated in an horizontal fashion with 1 or 2 stitches to normalize crural length. The indication to use a mesh was based on the presence of a large hiatal hernia, the subjective surgeon's feeling of weak crura, and the frailty of crura tissue noticed upon knotting the sutures. A pre-shaped, 7 × 10 cm biosynthetic mesh with a "U" configuration (Gore Bio A® tissue reinforcement, Flagstaff, AZ) was implanted over the hiatus surface and fixed to both crura with 2 or 3 non-absorbable sutures (Fig. 1a, b). This biodegradable mesh is composed of a porous 3-dimensional web of polymers (polyglycolic acid/

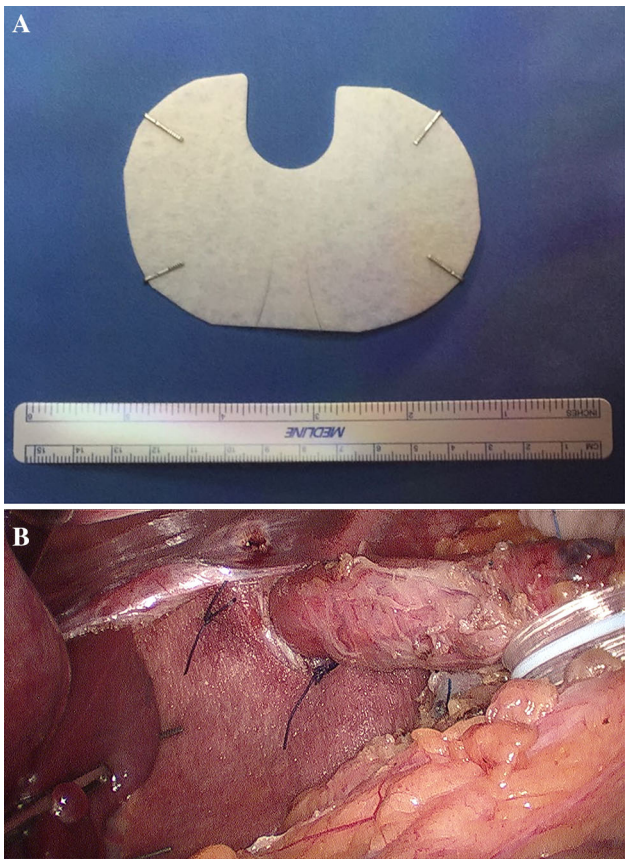

Fig. 1 **a** The Bio-A pre-shaped mesh can be trimmed as needed to fit over the crura surface and is marked at the corners with 4 metal clips for subsequent radiological identification. **b** Intraoperative image showing the Bio-A mesh in place and fixed to the crura with interrupted stitches

trimethylene carbonate), and is gradually absorbed over 6 months and replaced by vascularized soft tissue. Before implantation, the mesh was marked with metal clips at the corners to be recognized at X-rays. Finally, a 270° Toupet posterior fundoplication was routinely performed. The nasogastric tube was generally removed at the end of the procedure. A standardized postoperative protocol to prevent postoperative nausea and vomiting (Metoclopramide 10 mg, Ondasentron 4 mg, and Dexamethasone 8 mg intravenously) was routinely used.

Statistical analysis

Continuous data are presented as mean and standard deviation or median and IQR. Categorical variables are shown as numbers and percentages. Wilcoxon signed-rank for paired data was performed as appropriate. Two-sided p values were computed. Statistical significance was considered when p value was equal or less than 0.05. Confidence interval was set at 95% confidence level. Recurrence-free probability was estimated with the Kaplan–Meier method. Hazard ratio (HR) was estimated with univariate Cox proportional hazards model. Proportional hazard assumption was tested. All analyses were carried out using R version 3.2.2 software [11].

Results

Between September 2011 and March 2016, a total of 265 patients underwent laparoscopic repair of hiatal hernia and fundoplication at our institution. Patients in whom no mesh ($n = 148$) or mesh other than Bio-A ($n = 17$) were used, and those in whom hiatal hernia repair was combined with Nissen or Dor fundoplication ($n = 42$) were excluded from the study. Demographic characteristics and preoperative data of the 100 patients who fulfilled the criteria for inclusion are summarized in Table 1. Three of the 17 patients who presented with a recurrent hiatal hernia had multiple previous operations (two patients had 2 operations and one patient had 4 operations).

The median duration of surgery was 168 min (IQR = 80). All the operations were completed laparoscopically. Additional plication of the left crus was necessary before mesh placement in 11 patients with type III–IV hernia and a severely disrupted hiatus. There were no major intraoperative complications or mortality. The overall postoperative morbidity rate was 10%, and consisted of transient gastric distension ($n = 3$), pneumothorax ($n = 2$), atelectasis (2), atrial fibrillation ($n = 1$), hematoma at trocar site ($n = 1$), and acute urinary retention ($n = 1$). On postoperative day one, the plain film of the abdomen showed that the mesh was in the correct location in all patients (Fig. 2). A delayed gastric emptying on the gastrographin swallow study was noted in six patients; however, the nasogastric tube had to be reinserted only in three of these patients and was removed the next day. The median postoperative hospital stay was 2 days (IQR = 2), and all the patients were discharged with a soft diet (Table 2).

Table 1 Demographic and preoperative characteristics of the patient population

	$n = 100$
Sex, female (n)	83
Age, years (mean ± SD)	66.8 ± 10
BMI, kg/m^2 (mean ± SD)	27.2 ± 4.6
Comorbidities (n)	
Hypertension	55
Kyphoscoliosis	26
COPD	18
Diabetes	9
Symptom duration, years, median (IQR)	5 (8.5)
PPI therapy duration, years, median (IQR)	4 (7)
Previous blood transfusions (n)	13
Previous iron therapy (n)	16
Previously failed surgical repair (n)	17
Symptoms (n)	
Postprandial discomfort	80
Heartburn/regurgitation	73
Chest pain	31
Dyspnea	30
Anemia	26
Dysphagia	26
None	2
GERD-HRQL score, median (IQR)	14 (11)
Hernia type (n)	
Type I	10
Type II	3
Type III	81
Type IV	6
Hernia size, cm, median (IQR)	7 ± 2.5
Esophagitis (n, %)	16
Barrett's esophagus (n, %)	7

The median follow-up time was 30 (IQR = 22) months, and all patients had a minimum 6 months follow-up. Two patients died during the follow-up for unrelated reasons, and two were lost at the latest follow-up call (October 2016). Ninety-seven percent of patients underwent at least one upper gastrointestinal endoscopy or a barium swallow study (Fig. 3) after the operation, and 81% underwent at least two consecutive endoscopies.

No mesh-related complications were detected during the follow-up. The incidence of recurrent hernia ≥2 cm was 9%, and eight of the nine patients had a preoperative type III hernia. There were nine hernia recurrences ≥2 cm

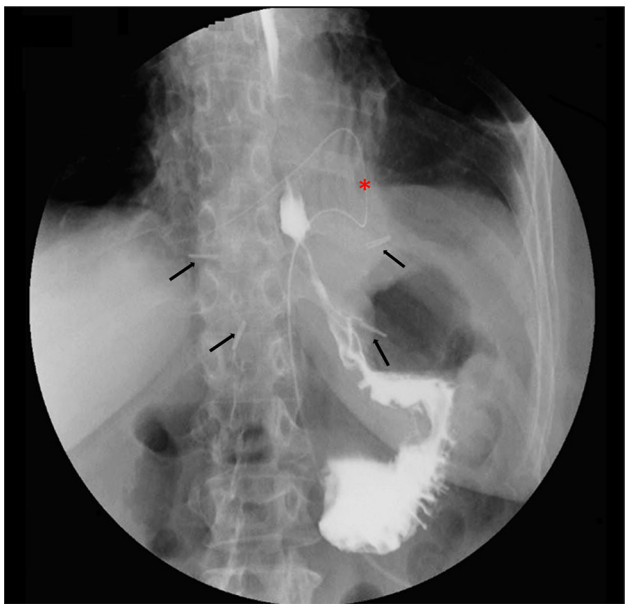

Fig. 2 Gastrographin swallow study on postoperative day one. The *arrows* indicate the 4 clips marking the corners of the mesh, and the *asterisk* indicates the mediastinal drain

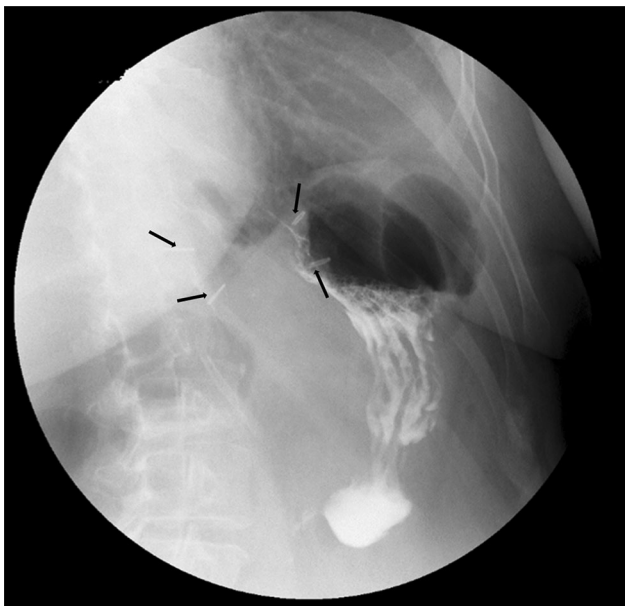

Fig. 3 Barium swallow study 3 years after surgery. The marking clips are still visible in the sub-diaphragmatic position

Table 2 Postoperative outcomes

	$n = 100$
Morbidity (*n*)	10
Hospital stay, days (IQR)	2 (2)
Follow-up, median (IQR)	30 (22)
Lost to follow-up (*n*)	4
Objective endoscopic/radiological testing ≥6 months (*n*)	97
Hernia recurrence (*n*)	9
Surgical revision (*n*)	0

detected by endoscopy and confirmed at barium swallow study. Of these patients, only two complained of mild reflux symptoms responding to PPI therapy. None of the patients required surgical revision. The recurrence-free probability at 12 months was 0.99 (CI 0.97–1.00), while at 58 months was 0.84 (CI 0.74–0.97) (Fig. 4). At univariate Cox regression analysis, age, BMI, hernia size, and previously failed surgical repair were not associated with anatomical recurrence (Table 3).

Figure 5 shows that GERD-HRQL scores were significantly reduced and returned to normal values compared to baseline (14, IQR = 11 vs 2, IQR = 4; $p < 0.001$); only six patients had a GERD-HRQL score greater than ten and required daily PPI therapy.

Among the 17 patients operated for a recurrent hiatal hernia, there was one symptomatic recurrence and one endoscopic recurrence detected 12 months after surgery. This patient was not symptomatic and did not require PPI use.

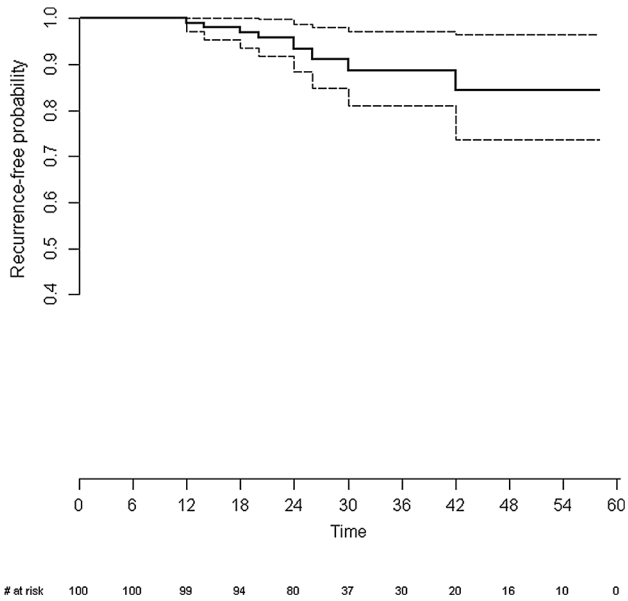

Fig. 4 Cumulative recurrence-free probability of hiatal hernia. *Dashed lines* represent 95% confidence bands

Discussion

In a previous study comparing primary cruroplasty and Bio-A mesh repair, both combined with either Toupet or Nissen fundoplication, we found an earlier failure rate in the non-mesh group 1 year after surgery [12]. The present study confirms that the use of an absorbable synthetic mesh was safe and durable over time in a larger patient population. No infectious or mechanical complication associated to the mesh were observed, and the median GERD-

Table 3 Univariate Cox proportional hazard analysis of variables affecting hernia recurrence

Variable	HR	CI	*p* value
Age	1.01	0.94–1.07	0.847
BMI	1.03	0.90–1.18	0.675
Hernia size	1.15	0.84–1.56	0.384
Previously failed repair	1.35	0.28–6.58	0.703

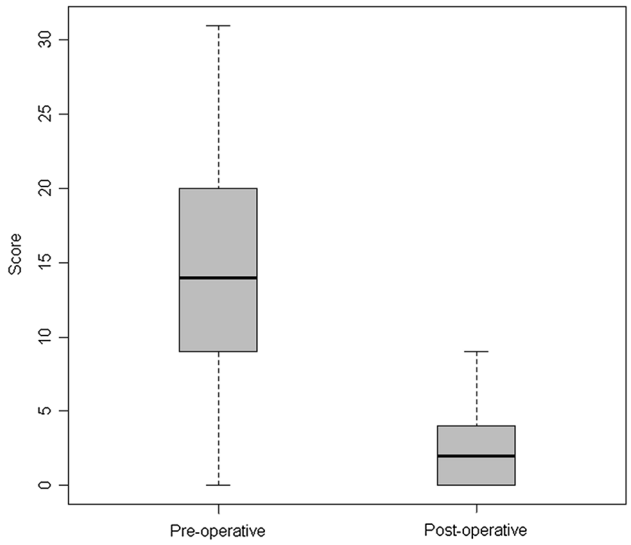

Fig. 5 GERD-HRQL median scores before and after hiatal hernia repair (Wilcoxon signed-rank test for paired data, $p < 0.001$)

HRQL score significantly decreased over the long-term follow-up. The systematic prevention of postoperative nausea and vomiting avoided perioperative recurrences in our series. Most anatomical recurrences were observed between 13 and 30 months after the operation, and, importantly, there was no need for reoperation in any of these patients because all of them remained minimally symptomatic. There was no clinical and statistical association between age, BMI, and previously failed antireflux repair on hernia recurrence.

Wang et al. [13] reported the 5-year outcomes of asymptomatic recurrences following laparoscopic repair of very large hiatal hernias. Patients with small hernia recurrences were more likely to report heartburn and use of proton pump inhibitors compared to controls without hernia, but they were still satisfied with the results of the operation and surgical revision rates were low.

Oelschlager et al. [14], in a randomized trial comparing primary repair and biological mesh repair, found that the recurrence rate at 6 months was significantly lower (9 vs 24%); however, subsequent follow-up at 5 years showed that recurrent rates did not differ (54 vs 59%) between the biological mesh and the primary repair group. The authors concluded that the mesh, although not protecting against anatomical recurrence, may decrease the risk of recurrent hernia requiring reoperation [15].

Lidor et al. [16] prospectively studied 111 patients after laparoscopic paraesophageal hernia repair with biological mesh-augmented suture cruroplasty combined with Nissen fundoplication with or without anterior gastropexy. Quality of life scores significantly improved during a mean follow-up time of 43.5 months. Radiographic hernia recurrence at 1 year was 27%, but only four (3.6%) of patients required reoperation. Large hernias were more likely to recur (OR 3.74) compared with those involving only the gastric fundus.

Our findings reflect the results of the previous studies, the difference being that the cumulative probability of recurrence in our experience was low and no reoperations occurred. In addition, in agreement with the findings of Zaninotto et al. [17], sequential endoscopies confirmed that most of our recurrences occurred after the first year of follow-up.

However, no conclusive evidence still exists to recommend mesh augmentation for hiatal hernia repair. A recent systematic review and meta-analysis comparing laparoscopic mesh and suture crura repair found that the "quality of evidence" supporting mesh cruroplasty is low because of heterogeneity of data and bias due to inconsistency of definition of hernia and hernia recurrence, subjective assessment of recurrence, and inaccurate reporting of revisional operations [18]. Interestingly, a recent randomized controlled trial comparing three methods of hiatus repair (standard cruroplasty vs synthetic vs biological mesh) reported no significant differences in hernia recurrence or clinical outcomes [19]. Also, the sustained improvement in quality of life was independent of mesh augmentation [20]. In contrast, a meta-analysis and risk–benefit analysis by Muller-Stich et al. showed that mesh application should be considered for laparoscopic paraesophageal hernia repair because it reduces recurrences, at least in the medium-term follow-up, and does not to increase complications and mortality [21].

A strength of the present cohort study is that all patients received the same type of absorbable synthetic mesh with the adjunct of a Toupet fundoplication, and were followed for a median of 30 months postoperatively. In addition, precise assessment of anatomical recurrence by objective follow-up was obtained and most patients underwent consecutive endoscopies.

Among the limitations of this observational retrospective study is that, despite the homogeneous patient population, selection bias cannot be excluded. Furthermore, a longer follow-up is required and the low number of

recurrences did not allow a multivariate Cox regression analysis to assess potential risk factors for recurrence.

In conclusion, this study confirms that laparoscopic crura augmentation with Bio-A mesh combined with a Toupet fundoplication is safe and effective in the medium-term follow-up, and is associated with a sustained improvement in quality of life even in patients with previously failed repairs. None of our patients required reoperation, and mesh reinforcement appeared to protect from early anatomical recurrences. The very long-term effectiveness of crura augmentation with the Bio-A mesh need to be further investigated in randomized clinical trials.

Compliance with ethical standards

Ethical approval All procedures involved in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest EA, AS, GB, AL, PM, and LB declare no conflict of interest.

References

1. Stylopoulos N, Rattner DW (2005) The history of hiatal hernia surgery: from Bowditch to laparoscopy. Ann Surg 241:185–193
2. Kaplan JA, Schecter S, Lin MYC, Rogers S, Carter JT (2015) Morbidity and mortality associated with elective or emergency paraesophageal hernia repair. JAMA Surg 150(11):1094–1096
3. Draaisma WA, Gooszen HG, Tournoij E, Broeders IA (2005) Controversies in paraesophageal hernia repair: a review of literature. Surg Endosc 19(10):1300–1308
4. Hashemi M, Peters JH, DeMeester TR et al (2000) Laparoscopic repair of large type III hiatal hernia: objective follow-up reveals high recurrence rate. J Am Coll Surg 190(5):553–560
5. Frantzides CT, Carlson MA, Loizides S et al (2010) Hiatal hernia repair with mesh: a survey of SAGES members. Surg Endosc 24:1017–1024
6. Antoniou SA, Antoniou GA, Koch OO, Pointner R, Granderath FA (2012) Lower recurrence rates after mesh-reinforced versus simple hiatal hernia repair: a meta-analysis of randomized trials. Surg Laparosc Endosc Percutan Tech 22:498–502
7. Stadlhuber RJ, Sherif AE, Mittal SK et al (2009) Mesh complications after prosthetic reinforcement of hiatal closure: a 28-case series. Surg Endosc 23(6):1219–1226
8. Kahrilas PJ, Kim HC, Pandolfino JE (2008) Approaches to the diagnosis and grading of hiatal hernia. Best Practice Res Clin Gastroenterol 22:601–616
9. Asti E, Bonavina L, Lombardi M, Bandera F, Secchi F, Guazzi M (2015) Reversibility of cardiopulmonary impairment after laparoscopic repair of large hiatal hernia. Int J Surg Case Rep 14:33–35
10. Velanovich V (1998) Comparison of generic (SF-36) vs disease-specific quality of life (GERD-HRQL) scales for gastroesophageal reflux disease. J Gastrointest Surg 2(2):141–145
11. R Development Core Team (2015) A language and environment for statistical computing. R Foundation for Statistical Computing, 2015. Vienna, Austria. ISBN 3-900051-07-0
12. Asti E, Lovece A, Bonavina L, et al (2016) Laparoscopic management of large hiatus hernia: 5-year cohort study and comparison of mesh-augmented versus standard crura repair. Surg Endosc 30:5404–5409
13. Wang Z, Bright T, Irvine T, Thompson SK, Devitt PG, Watson DI (2015) Outcome for asymptomatic recurrence following laparoscopic repair of very large hiatus hernia. J Gastrointest Surg 19:1385–1390
14. Oelschlager BK, Pellegrini CA, Hunter J et al (2006) Biologic prosthesis reduces recurrence after laparoscopic paraesophageal hernia repair: a multicenter, prospective, randomized trial. Ann Surg 244(4):481–490
15. Oelschlager BK, Pellegrini CA, Hunter JG et al (2011) Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial. J Am Coll Surg 213(4):461–468
16. Lidor AO, Steele KE, Stem M, Fleming RM, Schweitzer MA, Marohn MR (2015) Long-term quality of life and risk factors for recurrence after laparoscopic repair of paraesophageal hernia. JAMA Surg 150(5):424–431
17. Zaninotto G, Portale G, Costantini M et al (2007) Objective follow-up after laparoscopic repair of large type III hiatal hernia. Assessment of safety and durability. World J Surg 31:2177–2183
18. Tam V, Winger DG, Nason KS (2016) A systematic review and meta-analysis of mesh versus suture cruroplasty in laparoscopic large hiatal hernia repair. Am J Surg 21(1):226–238
19. Watson DI, Thompson SK, Devitt PG et al (2015) Laparoscopic repair of very large hiatus hernia with sutures vs absorbable vs non-absorbable mesh—a randomized controlled trial. Ann Surg 261:282–289
20. Koetje JH, Irvine T, Thompson S et al (2015) Quality of life following repair of large hiatal hernias is improved but not influenced by use of mesh: results from a randomized controlled trial. World J Surg 39(6):1465–1473
21. Muller-Stich BP, Kenngott HG, Gondan M et al (2015) Use of mesh in laparoscopic paraesophageal hernia repair: a meta-analysis and risk-benefit analysis. PLOS One. doi:10.1371/journal.pone.0139547