The follow-up and results of laparoscopic antireflux surgery

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Equal patient satisfaction, quality of life and objective recurrence rate after laparoscopic hiatal hernia repair with and without mesh

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ABSTRACT

INTRODUCTION Laparoscopic hiatal hernia repair has become standard practice for most surgeons performing antireflux surgery. Hiatal hernia repair consists of cruraplasty with sutures only, or additional reinforcement using mesh. Use of mesh was initiated to reduce recurrence rates. Recent analyses showed that use of mesh may influence radiologic recurrence rates, but it does not seem to prevent symptomatic recurrences and the need for reoperation. This study compares a cohort of patients regarding clinical and radiological outcomes of primary cruraplasty and cruraplasty with non-absorbable mesh after laparoscopic hiatal hernia repair.

METHODS Retrospective analysis of prospective followed patients after laparoscopic correction of hiatal hernia type II-IV in two tertiary referral centers. Radiologic recurrence, symptom atic recurrence, reoperation rate, complications and patient reported outcome measures were analyzed for all patients.

RESULTS 189 patients were analysed after laparoscopic hiatal hernia correction with an additional fundoplication (127 (67.2%) primary correction, 62 (32.8%) with mesh reinforcement). After a mean follow-up of 39.3 months the overall radiologic recurrence rate was 24.3% and equal in both groups (25.8% (mesh) versus 23.6% (no mesh) P=0.331). Symptomatic recurrence rate was 13.2% (16.1% versus 11.8%, p=0.495) and reoperation rate 7.4% (9.7% versus 6.3%), which was comparable between groups. Complications were equal and no serious mesh-related complications were seen. Health-related quality of life improved after surgery, dysphagia decreased and patient satisfaction was high for both groups without significant differences.

CONCLUSION Radiologic recurrence, symptomatic recurrence, and reoperation rate are equal with or without non-absorbable mesh reinforcement after laparoscopic hiatal hernia repair, irrespective of hernia size and type. Quality of life, dysphagia and patient satisfaction was comparable. No serious mesh-related complications occurred. The results of this study do not support routine use of mesh in hiatal hernia.

INTRODUCTION

Laparoscopic repair of large hiatal hernia has become standard therapy for patients with symptomatic hiatal hernia, and covered around 50% of laparoscopic antireflux procedures in the last decade.[1] Hiatal hernia is associated with impaired quality of life, caused by symptoms including dysphagia, chest pain, reflux, regurgitation and airway symptoms like cough and dyspnea. It is more common in the elderly patient with a higher incidence with increasing age.[2,3] Surgery consists of dissection of the hernial sac from the mediastinum into the abdomen, followed by cruraplasty with sutures and fundoplication.[4] This procedure has demonstrated acceptable morbidity and low symptomatic recurrence rate.[5-7] More recent studies providing radiologic follow-up with barium-swallow X-rays, reported high numbers of radiologic, asymptomatic recurrence hiatal hernia, with rates up to 30-42%.[8,9] Although only 5% of these patients had symptomatic recurrence. An asymptomatic recurrence can become symptomatic over time and can lead to severe c omplications like strangulation.[9,10] In attempt to reduce recurrence rates, several surgeons were looking for firmer crural repair using mesh. It showed promising results in the first clinical trials.[11-15] The use of mesh was associated with certain rare, but serious complications such as stenosis and erosion that could result in partial or total gastrectomy or even oesophagectomy.[16-19] For that reason, several randomised clinical trials have compared primary suturing versus prosthetic, non-absorbable and absorbable mesh, not just for comparing recurrence rates, but to analyse the incidence of mesh-related complications as well.[12-14,20] Two recent meta-analyses demonstrated that all procedures provide comparable results, with a possible favorable outcome for use of mesh in asymptomatic recurrence rate, but not for reoperation rate.[21,22] Patient satisfaction and quality of life was equal after primary cruraplasty, use of biologic absorbable mesh, and prosthetic non-absorbable mesh in a recent randomised controlled trial.[23]

This study describes the symptomatic and objective results of a large cohort of patients that underwent laparoscopic repair for a symptomatic type II-IV hiatal hernia. Data were prospective collected and retrospective analysed. In contrast to many studies we used patient reported outcome measures (PROM's), to evaluate patient satisfaction and quality of life after surgery. We hypothesised that clinical outcome between primary cruraplasty and cruraplasty reinforced with a non-absorbable mesh would be equal. Therefore, the aim was to analyse radiologic and symptomatic recurrence, and compare reoperations, complications, and PROM's to find which factors could be associated with symptomatic recurrence and reoperation.

MATERIALS AND METHODS

PATIENT SELECTION

Patients that underwent laparoscopic hiatal hernia repair of a type II, III or IV hiatal hernia with a minimal follow-up of six months were included in this study. All patients were operated in two tertiary referral centers for antireflux surgery (both centers >80 cases per year). Patients that were mentally incapable, younger than 18 years old at time of surgery, incapable to speak the Dutch language or patients that were diagnosed with a different disease during preoperative investigations or during surgery were excluded. Also, patients with previous antireflux surgery were excluded.

PREOPERATIVE WORKUP

The majority of patients were referred by the gastroenterologist. Preoperative upper gastrointestinal endoscopy, barium-swallow X-ray, and/or computed tomography (CT) were performed preoperative to confirm the diagnosis of hiatal hernia. Oesophageal manometry and 24-hours-pH-metric were only performed on clinical indication. Hiatal hernia was categorised according to the Guidelines for the management of hiatal hernia by the Society of American Gastrointestinal and Endoscopic Surgeons.[24]

DATA COLLECTION

Collection of data using questionnaires was prospective. Completion of data was done retrospective using electronic patient files. Comorbidity was categorised as presence of cardiovascular disease (including hypertension, cardiac arrhythmias, coronary artery disease, peripheral vascular disease, cerebrovascular disease); presence of diabetes mellitus (including type I and II); presence of Chronic Obstructive Pulmonary Disease (COPD); and a history of previous abdominal surgery (either laparoscopic or open surgery). Primary symptoms were categorised into dysphagia, airway symptoms (coughing and dyspnea), reflux, chest pain and anaemia.

SURGICAL TECHNIQUE

All procedures were performed laparoscopic, no conversions to laparotomy were needed. First step in the procedure was reduction of the stomach, and if present other abdominal organs, followed by dissection of the hernia sac. When exposure of the hiatus was gained and the oesophagus was sufficiently mobilised, posterior cural repair, and anterior repair when deemed necessary, was performed using non-absorbable sutures. When there was too insufficient or weak crural tissue, a U-shaped, non-absorbable mesh was used for posterior crural reinforcement (TiMESH®, pfm medical titanium gmbh, Nürnberg, Germany). This was fixed using non-absorbable sutures or absorbable tackers, while carefully avoiding direct contact to the oesophagus. In addition a fundoplication was performed to avoid recurrent reflux. According to the preference of the surgeon this was either a 180° anterior partial fundoplication (180°LAF),[25,26] a 270° posterior partial Toupet fundoplication (LTF)[27] or a 360° total Nissen fundoplication (LNF).[28]

FOLLOW-UP

Barium-swallow X-rays were performed three to six months postoperative. Postoperative endoscopy, CT, 24-hours-pH-metric, and/or oesophageal manometry were performed only on indication given the invasive character of these investigations. One hospital prospectively followed patients using validated questionnaires, including the validated Gastro-Esophageal Reflux Disease health related Quality of Life (GERD-hr-QoL) for GERD-related quality of life,[29-32] and the validated QLQ-OES-24 for scoring dysphagia.[33,34] Furthermore, symptoms were scored on a 10-point Visual Analogue Scales,[35] and assessed their satisfaction about preoperative information, quality of care (outpatient, surgical department, ward, etc), waiting time for the operation, and postoperative care on 10-point Visual Analogue Scales were assessed. Finally, patients were asked in retrospect if they would undergo the same operation again, should have undergone this operation earlier and if they would recommend this operation to a close relative or good friend with equal symptoms, knowing what the results are after surgery. Patients were asked to complete

these questionnaires preoperatively, and at three months postoperative, one year postoperative and then yearly up until five years postoperative. Data collection was either on paper or online.

STATISTICS

Parametrically distributed data were analysed using Student t tests. Non-parametric data were analysed using Mann-Whitney U tests. Categorical data were analysed using Fisher´s exact tests or Chi-square tests. Univariate logistic regression analyses were performed to predict risk factors. Multivariate logistic regressions were performed with factors that showed significant univariate regression ($P<0.05$). Statistical analyses were performed using IBM´s Statistical Package for Social Sciences (SPSS), version 22 for Apple Macintosh OS (IBM corp., Armonk, New York, USA). A p value of less than 0.05 was considered to be statistically significant.

ETHICAL APPROVAL

Patients gave informed consent and were informed about the purposes of the completed questionnaires and securely saved data. The Institutional Review Board of the hospitals has evaluated our study protocol and approved it without further obligations.

RESULTS

PATIENT CHARACTERISTICS

Between July 2009 and December 2015, a total of 189 patients with a mean age of 66.0 ± 11.2 years underwent laparoscopic hiatal hernia repair with additional fundoplication. Mean follow-up was 39.3 months ± 17.2. Patients were equally distributed over both hospitals (109 patients (57.7%) in hospital 1 versus 80 patients (42.3%) in hospital 2). 145 patients (76.7%) were female, 44 were male (23.3%), and mean body mass index (BMI) was 28.8 ± 4.3. Age, gender, and BMI did not differ between the two groups. The proportion of ASA II patients was higher in the non-mesh group and a higher percentage of ASA I and III in the mesh group ($P=0.038$). Presence of cardiovascular disease was higher in the non-mesh group ($P=0.008$). Indications for surgery for the overall group were dysphagia in 29.3% of patients, chest pain in 28.3%, reflux and regurgitation complaints in 20.1%, airway complaints like dyspnea or coughing in 17.4%, and anaemia or bleeding in 4.9% of patients. These indications for surgery were equal in the non-mesh and the mesh group. Hiatal hernia type and percentage of the stomach in the thoracic cavity was equal for both groups. The majority of patients had a type III hiatal hernia (67.2%) and more than 50% of the stomach displaced (77.1%). A non-absorbable mesh was used in 62 patients (32.8%). Baseline characteristics are described in table 1.

PERIOPERATIVE OUTCOME

Table 2 demonstrates perioperative outcome. The majority of patients received a 180° anterior fundoplication (67.9%), which was most frequently conducted in the non-mesh group (89.7% versus 23.0%). A Toupet fundoplication was performed in 30.5% of patients and more common in the mesh group (77.0% versus 7.9% in the non-mesh group; $P<0.001$). Laparoscopic Nissen fundoplication was performed in three cases of severe Barrett's oesophagus (2.4%). Intra-operative complications occurred in 9.8% of

TABLE 1. PATIENT CHARACTERISTICS				
		Mesh (n=62)	**No Mesh (n=127)**	**P-value**
Age[a]		64.1 ±12.8	66.9 ±10.3	0.140
Gender[b]	**Male**	15 (24.2%)	29 (22.8%)	0.856
	Female	47 (75.8%)	98 (77.2%)	
BMI[a]		28.9 ± 4.7	28.7 ± 4.2	0.873
ASA[a]	**I**	9 (14.5%)	10 (7.9%)	0.038
	II	38 (61.3%)	100 (78.7%)	
	III	15 (24.2%)	17 (13.4%)	
Comorbidity[b]	**Cardiovascular**	21 (33.9%)	70 (55.1%)	0.008
	Diabetes Mellitus	4 (6.5%)	10 (7.9%)	1.000
	Abdominal surgery	27 (43.5%)	65 (51.6%)	0.353
	COPD	10 (16.1%)	19 (15.0%)	0.832
Primary symptom[b]	**Dysphagia**	16 (27.1%)	38 (30.4%)	0.929
	Airway	12 (20.3%)	20 (16.0%)	
	Reflux	12 (20.3%)	25 (20.0%)	
	Chest pain	17 (28.8%)	35 (28.0%)	
	Anemia	2 (3.4%)	7 (5.6%)	
Hernia type[b]	**II**	6 (9.7%)	13 (10.2%)	0.483
	III	45 (72.6%)	82 (64.6%)	
	IV	11 (17.7%)	32 (25.2%)	
Percentage intra-thoracic stomach[b]	**0-24%**	1 (1.6%)	7 (5.6%)	0.113
	25-74%	26 (42.6%)	68 (72.3%)	
	75-100%	34 (55.7%)	51 (40.5%)	

BMI = Body Mass Index; ASA = American Society of Anesthesiologists physical status score; COPD = Chronic Obstructive Pulmonary Disease;
Data presented as either [a]:mean ± standard deviation, or [b]:number (percentage).

operations, without any major complications and were equal in both groups. Minor intra-operative complications consisted of asymptomatic pleural tear (3.2%, n=6); bleeding (1.6%, n=3); atrial fibrillation de novo (1.6%, n=3); small lesion of the spleen (1.1%, n=2); perforation of the oesophagus (0.5%; n=1); gastric perforation (0.5%; n=1). Complications were recognised and repaired if necessary. Median hospital stay was two days (IQR 2.0), and median duration of surgery was 100 minutes (IQR 42.5). Operation times were longer in the mesh-group (110 minutes versus 95 minutes; P=0.045). Postoperative complications were present in 11.6% of patients (n=22) and were equal in both groups. Postoperative complications consisted of urinary tract infection (2.6%; n= 5); pneumonia (1.6%; n=3); asymptomatic atelectasis (1.1%; n=2); pulmonary oedema (1.1%; n=2); dysphagia requiring reoperation in one case (1.1%; n=2); mediastinal bleeding requiring reoperation (0.5%; n=1); distal oesophageal stenosis requiring oesophageal stenting (0.5%; n=1);

recurrent hiatal hernia causing pain requiring reoperation (0.5%; n=1); and five other rare complications (e.g. pulmonary embolus, gastro-enteritis, oesophageal oedema, atrial fibrillation de novo, and constipation). There were no mesh-related complications during short- or long-term follow-up. Duration of follow-up was different between the two groups.

TABLE 2: PERIOPERATIVE CHARACTERISTICS AND OUTCOME

		Mesh (n=62)	No Mesh (n=127)	P-value
Fundoplication type[a]	**180°LAF**	14 (23.0%)	113 (89.7%)	<0.001
	LTF	47 (77.0%)	10 (7.9%)	
	LNF	0	3 (2.4%)	
Minor intra-operative complications[a]		5.0 (8.1%)	12 (9.4%)	1.000
Time of surgery[b]		110 (30)	95 (50)	0.045
Hospital days[b]		2.0 (2.0)	2.0 (2.0)	0.273
Postoperative complications[a]		8 (12.9%)	14 (11.0%)	0.810
Radiologic recurrence[a]		16 (25.8%)	30 (23.6%)	0.331
Symptomatic recurrence[a]		10 (16.1%)	15 (11.8%)	0.495
Reoperation[a]		6 (9.7%)	8 (6.3%)	0.393
Satisfaction after surgery (n=88)[b]		8.5 (3.0)	9.0 (2.0)	0.946
Follow-up after surger (months)[c]		49.2 (16.2)	34.5 (15.6)	<0.001

180°LAF = 180° anterior fundoplication
LTF = Toupet (270° posterior) fundoplicion
LNF = Nissen (360°) fundoplication
Data presented as either [a]: number (percentage), [b]: median (interquartile range), or [c]: mean (SD).

SYMPTOMATIC AND OBJECTIVE OUTCOME

109 patients were invited for follow-up using PROM's (57.7%). Response rate was 80.7% (n=88) and mean follow-up was 33.3 months ± 13.6. Median satisfaction of surgery was 9.0 (IQR 2.0) and equal in both groups. GERD-hr-QoL improved significant postoperatively (P≤0.001, n=77) from median 7.0 (IQR 15.0) preoperative, to 2.0 (IQR 2.0) postoperative. This improvement was equal for primary cruraplasty and use of mesh (figure 1). The QLQ-OES-24 also showed significant improvement after surgery (P<0.001, n=74) from 49 (IQR 15.0) to 34 (IQR 12.0). No differences were seen between the groups with crural repair with sutures only and the group with crural reinforcement using mesh (figure 2).Radiologic recurrence was investigated in 153 patients (81.0%). Radiologic recurrence was present in 46 patients (24.3%) and was equal for both groups (25.8%, n=16 in mesh versus 23.6%, n=30 in sutures; P=0.749). Symptomatic recurrence rate was 13.2% and equal in both groups as well (P=1.000). Reoperation rate was 7.4% (n=14) and comparable in the group with and without mesh. 13 reoperations were late (after > 4 weeks), mean time between primary operation and reoperation was 19.4 months ± 13.8, this was equal in the mesh- and sutures-group (P=0.902). Only one reoperation was done early (after five days). This was for acute recurrence of hiatal hernia with obstruction.

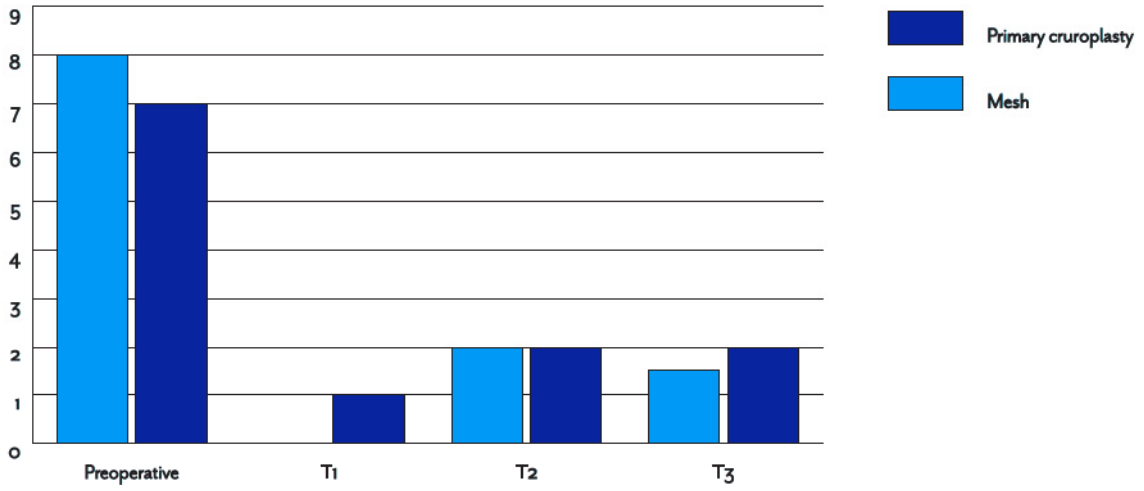

FIGURE 1. GERD-HR-QOL BEFORE AND AFTER LAPAROSCOPIC HIATAL HERNIA REPAIR

T1 = three months postoperative (n=69); T2 = 12 months postoperative (n=55); T3 = 24 months postoperative (n=32)
GERD-hr-QoL = Gastroesophageal Reflux Disease health-related quality of life questionnaire.
All postoperative scores show significant improvement compared to preoperative (P<0.001; preop vs T2 P=0.001).
No difference in postoperative scores. No difference between mesh and primary cruroplasty.

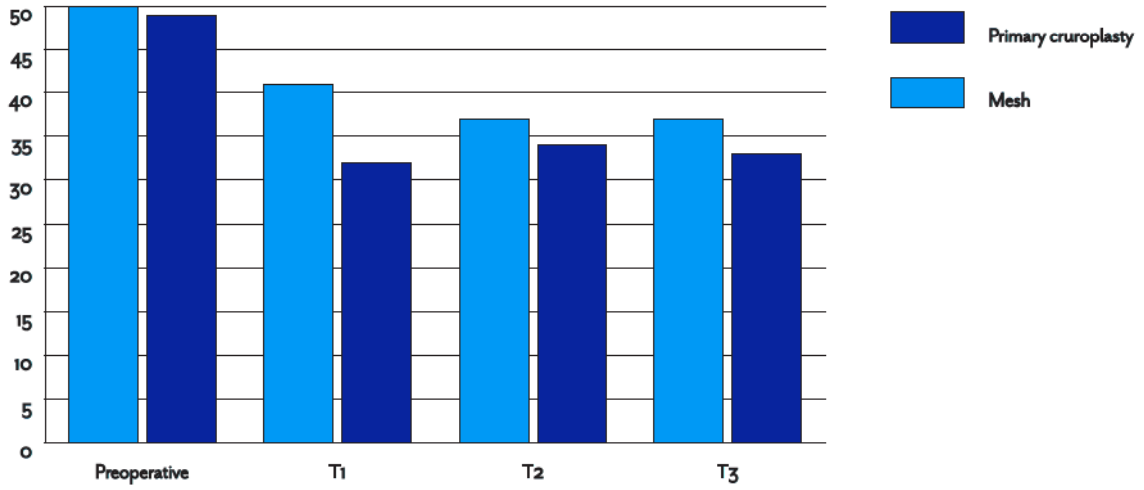

FIGURE 2. QLQ-OES24 SCORES BEFORE AND AFTER LAPAROSCOPIC HIATAL HERNIA REPAIR

T1 = three months postoperative (n=69); T2 = 12 months postoperative (n=55); T3 = 24 months postoperative (n=32).
QLQ-OES24 = Quality of Life questionnaire scoring dysphagia after surgery.
All postoperative scores show significant improvement compared to preoperative (P<0.001).
No difference in postoperative scores. No difference between mesh and primary cruroplasty.

RISK FACTOR ANALYSES

Univariate analyses demonstrated that age, BMI and previous abdominal surgery might be predictive factors for reoperation (table 3). Specific predictive factors for radiologic recurrence and symptomatic recurrence were not found. Use of mesh is not found to be a risk factor for radiologic recurrence, symptomatic recurrence or reoperation. Multivariate analyses showed comparable results and did not alter the influence of these predictive factors.

TABLE 3. UNIVARIATE ANALYSES						
	Radiologic recurrence		Symptomatic recurrence		Reoperation	
	OR (95% CI)	P-value	OR (95% CI)	P-value	OR 95% CI	P-value
Age	0.985 (0.954-1.017)	0.348	0.971 (0.936-1.007)	0.108	0.954 (0.912-0.998)	0.042
Sex	0.734 (0.334-1.611)	0.441	0.586 (0.233-1.469)	0.254	0.370 (0.121-1.131)	0.081
BMI	0.923 (0.848-1.005	0.065	0.942 (0.850-1.044)	0.256	0.869 (0.756-0.999)	0.049
ASA	1.106 (0.525-2.329	0.791	1.276 (0.563-2.894)	0.559	0.754 (0.260-2.186)	0.603
Cardiovascular comorbidity	1.019 (0.510-2.034)	0.958	1.440 (0.617-3.362)	0.399	0.794 (0.265-2.384)	0.681
Abdominal surgery history	0.727 (0.363-1.458)	0.369	0.453 (0.185-1.110)	0.083	0.260 (0.070-0.966)	0.044
Hernia type	0.766 (0.408-1.437)	0.406	0.989 (0.465-2.104)	0.977	0.825 (0.310-2.191)	0.699
Percentage intra-thoracic stomach	1.018 (0.778-1.331)	0.898	0.851 (0.610-1.186)	0.341	0.810 (0.526-1.247)	0.338
Fundo	1.637 (0.824-3.251)	0.159	1.291 (0.582-2.862)	0.529	1.433 (0.525-3.911)	0.483
Intra-operative complications	1.064 (0.348-3.257)	0.913	2.183 (0.651-7.323)	0.206	3.136 (0.782-12.573)	0.107
Mesh	1.505 (0.715-3.167)	0.282	1.410 (0.594-3.351)	0.436	1.594 (0.528-4.812)	0.408
Postoperative complications	0.542 (0.171-1.719)	0.298	1.026 (0.280-3.757)	0.969	1.292 (0.269-6.194)	0.749

BMI = Body Mass Index; ASA = American Society of Anesthesiologists physical status score; OR = Odds ratio; CI = confidence interval.

LARGE HIATAL HERNIAS

Table 4 shows a subanalysis of 85 patients suffering of a large hiatal hernia, categorised as more than 75% of intrathoracic stomach. Intra-operative and postoperative complication rates were comparable with the overall group, with no differences in complication rate between reinforcement with mesh and primary cruraplasty. Radiologic recurrence, symptomatic recurrence and reoperation rates were all equal in both groups, comparable with the analyses in the complete cohort.

TABLE 4. SUBANALYSIS FOR LARGE HIATHAL HERNIA (>75% INTRATHORACIC STOMACH); PERIOPERATIVE CHARACTERISTICS AND OUTCOME			
	Mesh (n=34)	No Mesh (n=51)	P-value
Minor intra-operative complications[a]	3 (8.8%)	5 (9.8%)	1.000
Time of surgery[b]	120 (43.3)	104 (45)	0.232
Hospital days[b]	2.0 (2.8)	2.0 (2.0)	0.949
Postoperative complications[a]	5 (14.7%)	5 (9.8%)	0.512
Radiologic recurrence[a]	8 (23.5%)	13 (25.4%)	0.749
Symptomatic recurrence[a]	4 (11.8%)	5 (9.8%)	1.000
Reoperation[a]	2 (5.9%)	4 (7.8%)	1.000

Data presented as either [a]:mean ± standard deviation, or [b]:number (percentage).

DISCUSSION

This study describes the results of a large cohort of patients suffering from a symptomatic hiatal hernia. After laparoscopic correction of these large hiatal hernias, radiologic recurrence rate was 24.3%, symptomatic recurrence rate was 13.2%, but only 7.4% of patients needed reoperation due to hiatal hernia recurrence. This was equal for primary cruraplasty and for cruraplasty with the use of prosthetic mesh. Univariate and multivariate analyses could not reveal a reduction of a symptomatic recurrence or reoperation rate with use of mesh. Age, previous abdominal surgery and body mass index were associated with higher symptomatic recurrence and reoperation. This is explained by difficulties during surgery in patients after previous abdominal surgery, higher BMI that is associated with higher complication rates after surgery, and weakening of muscular and fascia tissue with increasing age. However, a recent study demonstrated laparoscopic correction of large hiatal hernias to be safe in the elderly patient, when carefully selected.[36] Minor perioperative (9.8%) and postoperative complications (11.2%) were comparable in both groups and no major mesh-related complications occurred, similar with the previously mentioned trials. Only the time of surgery was significantly different between the groups. Prolonged operation time in the mesh-group was expected, as the reinforcement with mesh carries an extra step in the procedure. This was also described in the study of Frantzides et al,[12] but not in other studies nor in pooled data in meta-analyses.[7,13,21,22]

A subanalyis of the large hiatal hernias in this cohort showed comparable results. Except for time of surgery, which was prolonged for both procedures, but not significantly longer for repair with mesh when compared to primary cruraplasty. Patient reported satisfaction was high for both groups. Health related quality of life on both the reflux-scores (GERD-hr-QoL) and the dysphagia-scores showed significant improvement following surgery. All scores were comparable between primary cruraplasty and reinforcement with mesh.

This study demonstrates no difference in objective en symptomatic recurrence after laparoscopic hiatal hernia repair with primary cruraplasty versus non-absorbable mesh. This is in contrast to most previously published trials and meta-analyses. Granderath et al[13] and Frantzides et al[12] found lower recurrence rate with use of prosthesis compared to primary cruraplasty. Frantzides even found a 0% recurrence rate using a "keyhole" polytetrafluorethylene (PTFE) mesh, that surrounded the whole oesophagus. Since no long-term follow-up was reported, it is unclear whether mesh related complications occurred on later term or recurrence rates altered in time. Comparable reduction in recurrence rate has not been published yet. Two meta-analyses described higher recurrence rates after use of sutures only. Antoniou et al. found 24.3% recurrence following primary cruraplasty after six months, compared to 5.8% after use of mesh.[37] Furnee et al described comparable results with recurrence rate of 26.3% following primary crural correction and 14.6% with use of mesh.[38] Oelschlager et al reported promising results after six months using an absorbable mesh, with 9% recurrence in the mesh-reinforced group and 24% recurrence rate in the primary cruraplasty group.[14] But the five-year results that were published in 2011 revealed different numbers: 54% recurrence in the group that received a mesh, 59% recurrence in the group after primary correction.[15] Reoperation rates for recurrence were low: only 3.5% in the group after primary cruraplasty. Watson et al published 12 months results of a three-armed trial using primary correction, absorbable mesh and non-absorbable mesh, showing comparable results with our study. They found no difference in recurrence, radiologic nor symptomatic.[7]

Meta-analyses of Memon et al and Tam et al confirmed these findings.[21,22]
A possible weakness of this study is that the groups are not randomised for the different treatments. It was the surgeon's decision to perform primary cruraplasty or reinforce the cruraplasty with mesh. However, we did analyse both groups and did not find major differences in patient characteristics and perioperative characteristics. Primary symptoms, hiatal hernia size and percentage of intrathoracic stomach was equal in both groups. We therefore suggest that the groups are comparable. Another possible weakness might be the difference in fundoplication type, although it is not known that this could influence recurrence rate after hiatal hernia correction. In the univariate analyses fundoplication type did not influence recurrence rate. Duration of follow-up is not equal. Follow-up is shorter in the group without mesh, what can be explained due to the difference in group size and therefore more recent patients that underwent surgery without mesh. The majority of studies that describe results after laparoscopic hiatal hernia repair focus on clinical and objective outcome. However, patient-reported outcome measures (PROM's) like quality of life and satisfaction scores are important as a reflection of outcome that is more relevant to the individual patient.[39] Few studies describe quality of life using the Short-Form 36.[15,23] However, this might not be an adequate measure for symptom and quality of life alteration after laparoscopic antireflux surgery.[32] Health-related quality of life measures like the GERD-hr-QoL and the Gastrointestinal Quality of Life Index (GIQLI) and symptom scores using Visual Analog Scores are more reliable for outcome measurement. In our prospective data collection we use PROM's to evaluate outcome. This study describes significant improvement of health-related quality of life and high patient satisfaction, using validated questionnaires.
In conclusion: our study demonstrates comparable recurrence rates, both radiologic (objective) and symptomatic, after primary cruraplasty and mesh reinforced cruraplasty. Reoperation rate is also equal. Patient reported outcome measures reflecting patient satisfaction after surgery and quality of life are equal in both groups as well. The data in this study do not support the routine use of mesh. Randomised clinical trials comparing mesh and primary crural repair, using health-related quality of life measures and symptom scores, as well as radiologic versus symptomatic recurrence rates and reoperation rates have been undertaken. Long-term results of these randomised trials should be awaited before drawing definite conclusions about the use of mesh in hiatal hernia repair.

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