JAMA Surgery | Original Investigation

Hiatal Hernia Repair With Tension-Free Mesh or Crural Sutures Alone in Antireflux Surgery

A 13-Year Follow-Up of a Randomized Clinical Trial

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IMPORTANCE Antireflux surgery is an effective treatment of gastroesophageal reflux disease (GERD), but the durability of concomitant hiatal hernia repair remains challenging. Previous research reported that the use of a mesh-reinforced, tension-free technique was associated with more dysphagia for solid foods after 3 years without reducing hiatal hernia recurrence rates compared with crural sutures alone, but the long-term effects of this technique have not been assessed.

OBJECTIVE To assess the long-term anatomical and functional outcomes of using a mesh for hiatal hernia repair in patients with GERD.

DESIGN, SETTING, AND PARTICIPANTS A double-blind, randomized clinical trial was performed at a single center (Ersta Hospital, Stockholm, Sweden) from January 11, 2006, to December 1, 2010. A total of 159 patients were recruited and randomly assigned. Data for the current analysis were collected from September 1, 2021, to March 31, 2022. All analyses were conducted with the intention-to-treat population.

INTERVENTIONS Closure of the diaphragmatic hiatus with crural sutures alone vs a tension-free technique using a nonabsorbable polytetrafluoroethylene mesh (Bard CruraSoft).

MAIN OUTCOMES AND MEASURES The primary outcome was radiologically verified recurrent hiatal hernia after more than 10 years. Secondary outcomes were dysphagia scores (ranging from 1 to 4, with 1 indicating no episodes of dysphagia and 4 indicating more than 3 episodes of dysphagia per day) for solid and liquid foods, generic 36-Item Short Form Health Survey and disease-specific Gastrointestinal Symptom Rating Scale symptom assessment scores, proton pump inhibitor consumption, and reoperation rates. Intergroup comparisons of parametric data were performed using *t* tests; for nonparametric data, Mann-Whitney *U*, χ^2, or Fisher exact tests were used. For intragroup comparisons vs the baseline at follow-up times, the Friedman test was used, and post hoc analysis was performed using Wilcoxon matched pairs.

RESULTS Of 145 available patients, follow-up data were obtained from 103 (response rate 71%; mean [SD] age at follow-up, 65 [11.3] years; 55 [53%] female), with 53 initially randomly assigned to mesh reinforcement, and 50 to crural suture alone. The mean (SD) follow-up time was 13 (1.1) years. The verified radiologic hiatal hernia recurrence rates were 11 of 29 (38%) in the mesh group vs 11 of 35 (31%) in the suture group ($P = .61$). However, 13 years postoperatively, mean (SD) dysphagia scores for solids remained significantly higher in the mesh group (mean [SD], 1.9 [0.7] vs 1.6 [0.9]; $P = .01$).

CONCLUSIONS AND RELEVANCE Findings from this long-term follow-up of a randomized clinical trial suggest that tension-free crural repair with nonabsorbable mesh does not reduce the incidence of hiatal hernia recurrence 13 years postoperatively. This finding combined with maintained higher dysphagia scores does not support the routine use of tension-free polytetrafluoroethylene mesh closure in laparoscopic hiatal hernia repair for treatment of GERD.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT05069493

JAMA Surg. doi:10.1001/jamasurg.2023.4976
Published online October 11, 2023.

Visual Abstract
Invited Commentary
Supplemental content

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Laparoscopic antireflux surgery offers a safe and durable treatment of gastroesophageal reflux disease (GERD),[1-3] with several studies demonstrating excellent long-term results.[4,5] However, most patients with GERD referred for antireflux surgery present with a hiatal hernia,[6] and previous studies have reported recurrence of the hiatal hernia in up to 66% of cases,[7-9] especially among patients with large hiatal hernia.[9,10]

In order to reduce the risk of hiatal hernia recurrence, various types of synthetic absorbable or nonabsorbable meshes have been used to reinforce the hiatal closure,[11-14] albeit with diverging results.[15-17] Early randomized trials with short-term outcomes reported lower rates of hiatal hernia recurrence in patients with mesh reinforcement compared with crural closure using sutures only.[18-20] However, more recent studies with longer follow-up did not show significant differences.[21-23] Moreover, the use of mesh in the hiatal orifice carries the risk of serious complications, such as esophageal stenosis, mesh erosion, or fibrosis, leading to persistent dysphagia or pain.[24-26]

Members of our team previously reported the results of a double-blind randomized clinical trial with 3 years' follow-up in 159 patients with chronic GERD and a hiatal hernia with axial length longer than 2 cm who underwent laparoscopic antireflux surgery.[27] That study showed no difference between tension-free polytetrafluoroethylene (PTFE) mesh reinforcement and suture-only cruroplasty in terms of radiologically verified hiatal hernia recurrence. However, there was a statistically significant difference in dysphagia scores for solid food items at 3 years in favor of the suture group, implying that mesh reinforcement may expose the patient to a time-dependent increased risk of mechanical complications. We herein report the outcome from this trial cohort after more than 10 years of follow-up.

Key Points

Question Compared with the use of crural sutures alone, does tension-free closure of the hiatus with a nonabsorbable mesh in patients with hiatal hernia undergoing antireflux surgery for treatment of gastroesophageal reflux disease (GERD) reduce the risk of hiatal hernia recurrence 13 years postoperatively?

Findings In this follow-up of a randomized clinical trial of 159 patients with chronic GERD randomly assigned to the intervention group, follow-up data were obtained from 103. Radiologically verified hiatal hernia recurrence rates at 13 years were 38% for mesh and 31% for sutures alone, a nonsignificant difference, with long-term obstructive reports more common for mesh.

Meaning The present results do not support the routine use of tension-free mesh closure in laparoscopic hiatal hernia repair for GERD.

Methods

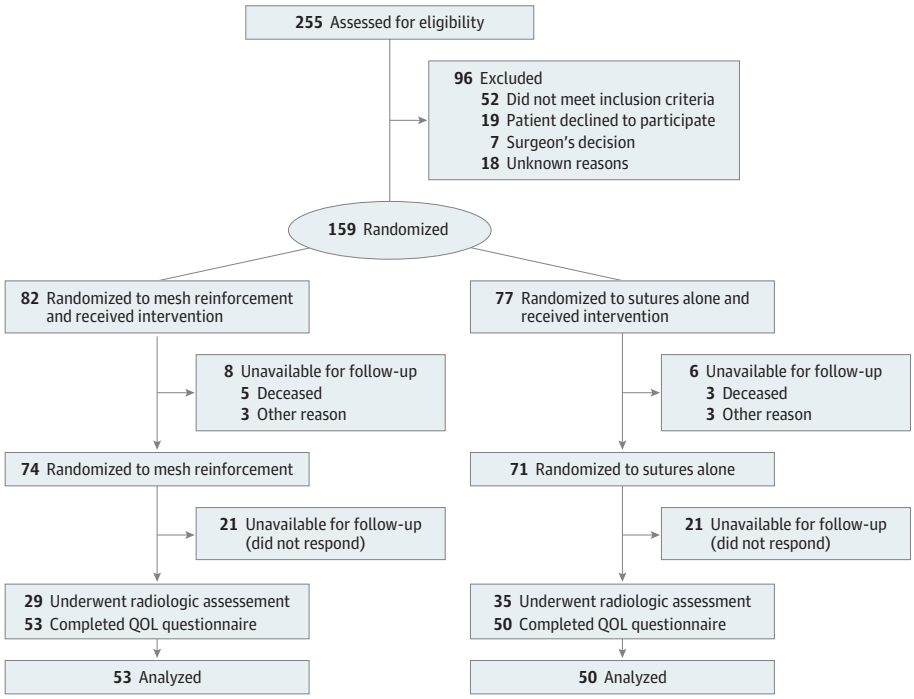
The original study protocol, patient characteristics, and clinical outcomes up to 3 years postoperatively have been described in detail previously.[27] The study protocol is provided in Supplement 1. In summary, patients with chronic GERD scheduled for elective laparoscopic antireflux surgery at the Department of Surgery, Ersta Hospital, Stockholm, Sweden, were screened for inclusion; the study was performed from January 11, 2006, to December 1, 2010. Study inclusion criteria were being older than 17 years, having objectively verified GERD, and having a hiatal hernia longer than 2 cm in axial length. Included patients were randomly assigned to either hiatal closure with interrupted sutures either with or without tension-free reinforcement with a PTFE mesh (Bard CruraSoft; large, triangular, 11 × 8 cm). The Regional Ethics Committee in Stockholm, Sweden, approved the study protocol, which was carried out in accordance with the Declaration of Helsinki.[28] Patients were asked by mail to participate in the study, and those who were willing to do so returned their signed informed consent together with the completed study questionnaires. Patients were also asked if they were willing to undergo a computed tomography (CT) scan examination. The study followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline.[29]

All participating surgeons (including B.S.H. and A.T.) had previous experience in antireflux surgery, with at least 25 operations performed by each. The laparoscopic repair included complete dissection and mobilization of the hernia sac and the mediastinal esophagus to allow at least 3 cm of the distal esophagus to rest without tension in the abdomen. For patients allocated to the suture group, the crural defect was closed using at least 3 interrupted nonabsorbable sutures, with caution taken not to strangulate the crural muscle when the sutures were tightened. In the mesh group, the pillars were approximated only when the maximal transverse width of the hiatus was more than 5 cm. If so, the hiatal opening was reduced to 5 cm using sutures as described above. The PTFE mesh was placed on the crus behind the esophagus and secured with at least 3 sutures and 10 to 15 ProTack staples (Covidien Sverige). Finally, in both groups, a Nissen fundoplication was constructed, without the use of a bougie, as described previously.[27]

For the present long-term follow-up study, data were collected from September 1, 2021, to March 31, 2022, and patients who were still available were invited to participate. Patients who were deceased or had emigrated were excluded. The primary outcome was radiologically verified recurrence of hiatal hernia at the time of follow-up. Secondary outcomes were quality of life, reflux and other abdominal symptoms, proton pump inhibitor (PPI) consumption, and reoperation rates.

For radiologic assessment of the hiatal anatomy, patients were previously investigated using a barium swallow study at 1 and 3 years after the surgery.[27] For the present study 13 years after the surgery, a CT scan of the upper abdomen was performed. Patients who received a reoperation due to recurrence of the hiatal hernia during the follow-up were not excluded from the radiologic investigation. A recurrent hiatal hernia was defined as any part of the stomach being located above the diaphragmatic level. The axial length of the hiatal hernia recurrence was measured. Quality of life and symptoms were assessed by using the same validated questionnaires as in the original study.[27] This included the Swedish version of the generic 36-Item Short Form Health Survey (SF-36),[30,31] the disease-specific Gastrointestinal Symptom Rating Scale (GSRS),[32] and

Figure 1. Flowchart of Patients Enrolled in the Trial



QOL indicates quality of life.

a specific dysphagia score questionnaire (scores range from 1 to 4, with 1 indicating no episodes of dysphagia and 4 indicating more than 3 episodes of dysphagia per day).[33,34]

For SF-36 responses, data are presented as physical component scores (PCSs) and mental component scores (MCSs). Each subscale score reached a maximum value of 100, with higher values reflecting better health status. The GSRS is a validated questionnaire containing 5 dimensions of abdominal symptoms (gastroesophageal reflux, abdominal pain, indigestion, obstipation, and diarrhea). Each subscale was presented as a 7-point Likert scale, with higher values representing more severe symptoms, and the mean item scores of the respective domains were used for analyses.

For dysphagia scoring, a standardized specific instrument was used that included a 4-point graded scale to describe dysphagia for solid and liquid food components,[27,33,34] with 1 indicating no episodes of dysphagia; 2, less than 1 episode of dysphagia per day; 3, 1 to 3 episodes of dysphagia per day; and 4, more than 3 episodes of dysphagia per day. This assessment of swallowing is a slight modification of the original method described[34] and was consistently used thereafter.[27,33]

Blinding

Patients, staff, and clinical assessors were blinded to the study group allocation, and the blinding was not broken during the entire study period, provided that no emergencies in the clinical management of the disorder so required. No such need was encountered during follow-up.

Statistical Analysis

All patients were analyzed on an intention-to-treat basis. Values are presented as means and SDs unless otherwise stated. Intergroup comparisons of parametric data were performed by use of 2-sided *t* tests, whereas for nonparametric data, Mann-Whitney *U*, χ^2, or Fisher exact tests were used when appropriate. For intragroup comparisons vs the baseline at the various follow-up time points (repeated measures), the Friedman test was used, and post hoc analysis was performed using the Wilcoxon matched-pairs test. All *P* values were 2-sided, and $P < .05$ was considered statistically significant. Patients with missing values were not included in the analysis for the time point or points at which data were missing. Statistical analysis was performed using the software package SPSS, version 26.0 (SPSS Inc).

Results

Initially, 159 patients were randomly assigned in the study, of whom 82 were allocated to the mesh group, and 77 to the sutures alone group. The flowchart of patients enrolled in the follow-up study is presented in **Figure 1**. Of 159 patients, 145 were available for follow-up and invited to participate (8 patients were deceased, and 6 patients were not available for other reasons). Two patients in the mesh group and 1 patient in the suture group died of cardiopulmonary causes, 1 patient in the mesh group died of malignant neoplasm (stomach), and the causes of death were unidentified in 2 patients in the mesh group and 2 patients in the suture group. The final response rate was 103 of 145 (71%). Of 103 patients included in the present follow-up study (mean [SD] age at follow-up, 65 [11.3] years; 55 [53%] female and 48 [47%] male), 53 were initially allocated to the mesh group, and 50 to the suture alone group. Baseline demographic characteristics of included patients are

presented in **Table 1**. The mean (SD) follow-up time was 13 (1.1) years in both groups.

During follow-up, 3 patients (6%) underwent reoperation in the mesh group, and 4 patients (8%) in the suture group, all due to recurrent GERD (P = .71). None of the included patients required re-operation due to mesh-induced complications, such as local erosion or penetration at the gastroesophageal junction. A CT scan of the upper abdomen and chest was carried out 13 years after surgery for 64 patients, of whom 29 were initially allocated to mesh reinforcement, and 35 to suture closure alone. **Table 2** gives the details of hiatal hernia recurrences over time for patients who underwent radiologic investigation (barium swallow study or CT scan) at the respective time points. There was a continuous increase in the number of anatomical recurrences during the follow-up, with recurrence rates of 3 of 41 (7%) at 1 year, 4 of 39 (10%) at 3 years, and 11 of 29 (38%) at 13 years in the mesh group, and 1 of 45 (2%) at 1 year, 3 of 44 (7%) at 3 years, and 11 of 35 (31%) at 13 years in the suture group. The sizes of most recurrent hiatal hernia were small and not different between the 2 repair groups.

The mean dysphagia scores for solid and liquid food items during the entire follow-up period are presented in **Table 3**. At 1 year after surgery, the dysphagia scores for both solid and liquid foods were lower in the suture alone group, whereas only the dysphagia scores for solids were statistically significantly lower in the suture group 3 years postoperatively. At 13 years after surgery, there was still a statistically significant difference between the groups in dysphagia scores for solids in favor of the suture alone group (mean [SD], 1.9 [0.7] for mesh vs 1.6 [0.9] for sutures; P = .01). Compared with baseline, there were statistically significant improvements in dysphagia scores for both solids and liquids only in the suture group at 1 and 3 years postoperatively. However, those improvements were not detected at 13 years of follow-up.

At 13 years after surgery, all the scores in the various domains of the GSRS were low, without any statistically significant differences between the 2 groups (eTable 1 in Supplement 2). The scores in the reflux domain were immediately and markedly reduced after surgery and remained so throughout the long-term follow-up. For the remaining domains, abdominal pain and indigestion scores were also significantly improved in both groups compared with baseline values at 13 years postoperatively, whereas there was no change compared with baseline for the obstipation and diarrhea domains.

The percentages of patients who consumed daily PPI 13 years after surgery were 14 of 53 (26%) in the mesh group and 7 of 50 (14%) in the suture group (P = .15). More reflux symptoms were observed among patients with a recurrent hiatal hernia compared with those without, whereas there were no differences in dysphagia scores nor in daily PPI intake (eTable 2 in Supplement 2).

The SF-36 scores recorded during the 13 years following surgery are presented in **Figure 2**. Both the physical (PCS) and mental (MCS) mean component scores were significantly improved compared with baseline at 1 and 3 years after surgery, without statistically significant differences between the groups. At 13 years after surgery, there were still no differences between the 2 groups in PCS or MCS scores on the SF-36. However, compared with baseline, PCS as well as MCS scores were improved in the suture group, whereas only MCS scores remained improved in the mesh group (MCS mean [SD], 47.8 [10.8] vs baseline 40.5 [12.8]; P = .002).

Table 1. Baseline Characteristics of Patients With Crural Repair With Mesh Reinforcement or Sutures Alone

Characteristic	Participants, No. (%)	
	Mesh repair (n = 53)	Suture alone (n = 50)
Age at operation, mean (SD), y	53 (10.4)	52 (12.4)
Age at follow-up, mean (SD), y	66 (10.5)	65 (12.2)
Follow-up, mean (SD), y	13 (1.1)	13 (1.1)
Sex		
Male	27 (51)	21 (42)
Female	26 (49)	29 (58)
BMI, mean (SD)	28.0 (3.3)	27.1 (3.1)
Radiology		
Hiatal hernia length, mean (SD), cm	4.5 (1.9)	5.3 (3.0)
Hiatal hernia size		
>4 cm	19 (36)	19 (38)
<4 cm	34 (64)	31 (62)
Barrett esophagus		
Yes	10 (19)	7 (14)
No	43 (81)	43 (86)
Total acid exposure, median (IQR), % of time pH <4	9.8 (6.5-18.4)	8.8 (6.4-12.6)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

Discussion

In this long-term (13-year) follow-up of a double-blind randomized clinical trial for patients with chronic GERD who underwent laparoscopic fundoplication, the durability of the repair of type 1 hiatal hernia of more than 2 cm in axial length with either crural sutures alone or by a tension-free repair reinforced with a nonabsorbable mesh was compared. An accumulated recurrence rate of hiatal hernia of 8% after 3 years was found, which increased to 38% in the mesh and 31% in the sutures alone group after another 10 years. Patients receiving sutures alone had less dysphagia for solids than patients in whom the hiatal closure was reinforced with a mesh, and reflux symptoms were equally well controlled by the Nissen fundoplication regardless of the hiatal repair technique. Moreover, improvements in health-related quality of life assessments were also similar during the entire follow-up. For patients with repeated recordings of the size of recurrent hiatal hernia over time, there was no progression in this respect beyond 3 years of follow-up.

The previously reported[27] downside of the mesh repair, with more dysphagia for solids at 1 and 3 years postoperatively, remained after 13 years of follow-up. It is likely that this difference is of clinical relevance, and the question arises of whether the finding indicates a local reaction in the gastroesophageal junction area induced by the implanted foreign material. However, during the entire follow-up, we identified no patient with

Table 2. Hiatal Hernia Recurrence at 1, 3, and 13 Years of Follow-Up After Laparoscopic Nissen Fundoplication With Mesh Reinforcement or Suture Alone

	Time since initial surgery					
	1 y		3 y		13 y	
Variable	Mesh (n = 41)	Suture (n = 45)	Mesh (n = 39)	Suture (n = 44)	Mesh (n = 29)	Suture (n = 35)
Recurrent hiatal hernia, No. (%)	3 (7)	1 (2)	4 (10)	3 (7)	11 (38)	11 (31)
Hiatal hernia size, mean (SD), cm	6.7 (3.1)	10.0 (NA)	6.0 (2.8)	6.3 (4.0)	4.4 (1.5)	3.4 (1.1)
P value for recurrence	.34		.70		.61	
Odds ratio (95% CI) for recurrence	3.47 (0.35-34.80)		1.56 (0.33-7.46)		1.33 (0.47-3.76)	
P value for size of hiatal hernia	.35		.86		.10	

Abbreviation: NA, not applicable.

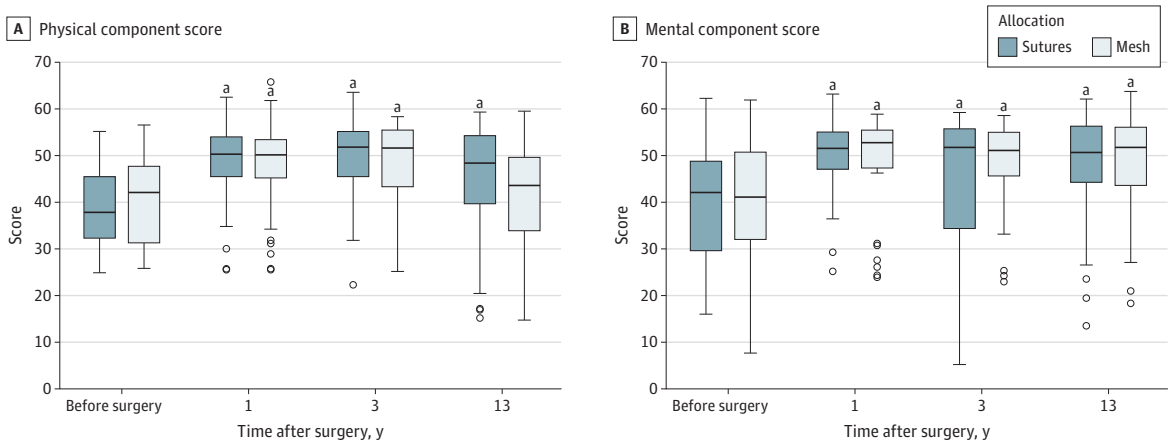
Table 3. Dysphagia Scores for Solid and Liquid Foods at Baseline and 1, 3, and 13 Years After Laparoscopic Nissen Fundoplication[a]

		Dysphagia score, mean (SD)							
				Time since surgery					
Food	Intervention	Baseline	*P* value between interventions	1 y	*P* value between interventions	3 y	*P* value between interventions	13 y	*P* value between interventions
Solid	Mesh	1.8 (1.0)	.61	1.7 (1.0)	.007	1.7 (0.8)	.006	1.9 (0.7)	.01
	Sutures only	1.7 (0.9)		1.3 (0.6)[b]		1.3 (0.7)[b]		1.6 (0.9)	
Liquid	Mesh	1.6 (0.9)	.35	1.4 (0.7)	.02	1.3 (0.7)	.14	1.4 (0.6)	.14
	Sutures only	1.4 (0.7)		1.1 (0.5)[b]		1.2 (0.5)[b]		1.3 (0.7)	

[a] Dysphagia was scored on a scale of 1 to 4, with 1 indicating no episodes of dysphagia and 4 indicating more than 3 episodes of dysphagia per day.

[b] *P* < .05 vs baseline.

Figure 2. Health-Related Quality of Life as Assessed by the 36-Item Short Form Health Survey 13 Years After Laparoscopic Nissen Fundoplication



Patients were allocated to crural suture repair with or without nonabsorbable polytetrafluoroethylene mesh reinforcement. In box and whisker plots, the horizontal line represents the median; box, 25th and 75th quartiles; whiskers, 10th to 90th percentile range; circles, outliers.

[a] *P* < .05 vs baseline.

local erosion or penetration at the gastroesophageal junction induced by the prosthetic device and no reoperation was required due to any local mesh-induced complication.

The overall rate of 34% of hiatal hernia recurrence for both groups at 13 years after the operation might be considered high, but other randomized trials with long-term follow-up have shown similar or even higher rates.[21,22] Likewise, in a recent meta-analysis of randomized clinical trials with long-term follow-up, 30.7% and 31.3% recurrence rates were reported after mesh augmentation and after suture repair only, respectively.[23] Most information regarding durability of hiatal hernia repair emanates from studies of patients with large paraesophageal hiatal hernias. It can be argued that the underlying mechanisms behind recurrence in type 1 hernias compared with paraesophageal herniations may differ.[10] However, the current observations imply that at least the magnitude of the problem with recurrence over time resides in the same range.

Control of reflux symptoms, as assessed by the GSRS, were equally well achieved by the 2 hiatal hernia repair techniques, and the effects on health-related quality of life assessments were without marked differences. These effects were

maintained in both groups during 13 years of follow-up, with the difference that the MCS domain of the SF-36 score was significantly improved only in the mesh group 13 years after the operation. The efficacy of both operations to control GERD was confirmed also by the pronounced and sustained effect on 24-hour ambulatory intraesophageal pH measurements at 3 years given in our previous report.[27] The potential surrogate marker for unsatisfactory reflux control (ie, PPI consumption) was approximately 10% during the first 3 years of follow-up,[27] with a 2-fold increase during the ensuing 10 years. Previous observations demonstrate that far from all persons who are prescribed PPI after antireflux surgery do in fact have recurrent GERD.[35-37] There were no statistically significant differences in PPI consumption between patients with or without a hiatal hernia recurrence, but the numbers were too few to allow for any firm conclusions.

The pathophysiological role of hiatal hernia in the development and severity of GERD has become increasingly evident.[38,39] Displacement of the gastroesophageal junction to the chest affects the reflux-protective function of the lower esophageal sphincter, with gastroesophageal reflux as a result, and the larger the hiatal hernia the more severe becomes the reflux.[6] Accordingly, hiatal closure is considered to be a critical component in the surgical treatment of GERD,[2,7,8] albeit hiatal hernia repair by cruroplasty alone does not offer control of GERD.[40-42] Our finding of worse GSRS reflux scores in patients with hiatal hernia recurrence reinforces the significance of the durability of the anatomical reconstruction. On the contrary, it is still unclear whether any anatomical relapse of hiatal hernia after antireflux surgery translates to recurrence of symptoms during a substantial period of time.[43-45] Further identification of the anatomical and functional predictors behind clinical failure after surgical treatment of hiatal hernia is an important issue that needs to be addressed in future studies.

Limitations and Strengths

Limitations of this study include the low number of patients who accepted and underwent a CT investigation to detect hiatal hernia recurrence. Many of the enrolled patients had the baseline hiatal hernia diagnosed and anatomically assessed through the use of endoscopy and barium swallow radiology and not by a CT scan. These facts may introduce some difficulties in head-to-head comparisons of the 2 techniques for hiatal hernia diagnosis and size assessments. Moreover, assessment of changes in the size of individual hiatal hernia recurrences over time may be imprecise. Nevertheless, the CT technique carries the sensitivity of detecting the prevalence of defects in the hiatal anatomy, allowing for a more accurate estimate of the late hiatal hernia recurrence rate. The limited number of available patients may also introduce pitfalls in the interpretation of the differences in quality of life over time. This limitation may be of particular importance when it comes to the clinical relevance of hiatal hernia recurrences per se. The main strengths of the study are that it was a randomized clinical trial using double blinding, which was maintained throughout the entire study period, and that the study was conducted at a high-volume tertiary referral center with high quality and standardization of surgical care.

Conclusions

In conclusion, this 13-year follow-up of a randomized clinical trial found that tension-free crural repair with nonabsorbable mesh did not reduce the incidence of recurrent hiatal hernia compared with crural sutures alone among patients with GERD undergoing a Nissen fundoplication. This finding combined with maintained higher dysphagia scores, also at 13 years postoperatively, does not support the routine use of tension-free PTFE mesh closure in laparoscopic hiatal hernia repair for GERD.

ARTICLE INFORMATION

Accepted for Publication: July 26, 2023.

Published Online: October 11, 2023. doi:10.1001/jamasurg.2023.4976

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Concept and design: Analatos, Håkanson, Ansorge, Lundell, Thorell.
Acquisition, analysis, or interpretation of data: Analatos, Håkanson, Ansorge, Lindblad, Thorell.
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Critical review of the manuscript for important intellectual content: All authors.
Statistical analysis: Analatos, Håkanson, Ansorge, Thorell.
Obtained funding: Håkanson, Thorell.
Administrative, technical, or material support: Håkanson, Ansorge, Thorell.
Supervision: Håkanson, Ansorge, Lindblad, Lundell, Thorell.

Conflict of Interest Disclosures: None reported.

Funding/Support: Dr Analatos reported receiving grants from the Centre for Clinical Research Sörmland, Uppsala University. Dr Thorell reported receiving grant 2006-0802 from Stockholm City Council and grant 140604 from the Erling-Persson Foundation.

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Data Sharing Statement: See Supplement 3.

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