Repair of Paraesophageal Hiatal Hernias—Is a Fundoplication Needed? A Randomized Controlled Pilot Trial

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BACKGROUND: The need for a fundoplication during repair of paraesophageal hiatal hernias (PEH) remains unclear. Prevention of gastroesophageal reflux represents a trade-off against the risk of fundoplication-related side effects. The aim of this trial was to compare laparoscopic mesh-augmented hiatoplasty with simple cardiophrenicopexy (LMAH-C) with laparoscopic mesh-augmented hiatoplasty with fundoplication (LMAH-F) in patients with PEH.

STUDY DESIGN: The study was designed as a patient- and assessor-blinded randomized controlled pilot trial, registration number: DRKS00004492 (www.germanctr.de/). Patients with symptomatic PEH were eligible and assigned by central randomization to LMAH-C or LMAH-F. Endpoints were postoperative gastroesophageal reflux, complications, and quality of life 12 months postoperatively.

RESULTS: Forty patients (9 male, 31 female) were randomized. Patients were well matched for baseline characteristics. At 3 months, the DeMeester score was higher after LMAH-C compared with LMAH-F (40.9 ± 39.9 vs. 9.6 ± 17; $p = 0.048$). At 12 months, the reflux syndrome score was higher after LMAH-C compared with LMAH-F (1.9 ± 1.2 vs. 1.1 ± 0.4; $p = 0.020$). In 53% of LMAH-C patients and 17% of LMAH-F patients, postoperative esophagitis was present ($p = 0.026$). Values of dysphagia (2.1 ± 1.6 vs 1.9 ± 1.4; $p = 0.737$), gas bloating (2.6 ± 1.4 vs 2.8 ± 1.4; $p = 0.782$), and quality of life (116.0 ± 16.2 vs 115.9 ± 15.8; $p = 0.992$) were similar. Relevant postoperative complications occurred in 4 (10%) patients and did not differ between the groups.

CONCLUSIONS: Laparoscopic repair of PEH should be combined with a fundoplication to avoid postoperative gastroesophageal reflux and resulting esophagitis. Fundoplication-related side effects do not appear to be clinically relevant. Multicenter randomized trials are required to confirm these findings. (J Am Coll Surg 2015;221:602–610. © 2015 by the American College of Surgeons)

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Since the minimally invasive approach to the repair of paraesophageal hiatal hernias (PEH) was introduced by Cuschieri and colleagues[1] in 1992, laparoscopic PEH repair has gained rapid acceptance as a standard method. With implementation of meshes into hiatal hernia surgery, a significant reduction in recurrences could be achieved.[2]

The need for fundoplication as a routine adjunct to PEH repair continues to be a controversial issue. Arguments for fundoplication include the prevalence of gastroesophageal reflux disease (GERD) in up to 80% of PEH patients and the risk of increased postoperative gastroesophageal reflux after PEH repair in about 30% of patients with no previous history of GERD.[3,4] In addition, fundoplication is thought to support the anchoring of the cardia below the diaphragm, thereby reducing the

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Abbreviations and Acronyms

ASA = American Society of Anesthesiologists
GERD = gastroesophageal reflux disease
GIQLI = Gastrointestinal Quality of Life Index
GSRS = Gastrointestinal Symptom Rating Scale
LMAH-C = laparoscopic mesh-augmented hiatoplasty with cardiophrenicopexy
LMAH-F = laparoscopic mesh-augmented hiatoplasty with fundoplication
PEH = paraesophageal hiatal hernias
PPI = proton pump inhibitor

risk of recurrence. For all these reasons, routine addition of fundoplication is commonly recommended. However, it might be possible that simple mesh-augmented restoration of the anatomy in patients with PEH resolves pre-existing GERD.[5,6] Even more important, there is a risk of fundoplication-related complications and side effects. The frequency of gas-bloating symptoms after fundoplication are reported to be up to 58%,[7] and in about 20% of patients, new symptoms occur postoperatively.[8,9] Therefore, intended improvement of GERD represents a trade-off against the risk of fundoplication-related side effects.

The question arises as to whether routine addition of a fundoplication is reasonable. To date, randomized data are not yet available. Therefore, the aim of this first randomized controlled pilot trial was a comparison of laparoscopic mesh-augmented hiatoplasty with simple cardiophrenicopexy (LMAH-C) to laparoscopic mesh-augmented hiatoplasty with fundoplication (LMAH-F) in patients with PEH regarding gastroesophageal reflux, side effects, complications, and quality of life.

METHODS

Trial design and patient selection

Because data on the effect of a fundoplication following mesh-augmented PEH repair were not available when this study was initiated, a reasonable power calculation was not possible. Therefore, this study was designed as a patient- and assessor-blinded randomized controlled pilot trial. The trial was conducted in 2 participating centers (University of Heidelberg, Germany and Kantonsspital St Gallen, Switzerland) between March 2007 and November 2011. Patients with symptomatic PEH (paraesophageal involvement was confirmed intraoperatively) were eligible. Exclusion criteria were axial sliding hiatal hernias, missing informed consent, previous hiatal hernia surgery, American Society of Anesthesiologists (ASA) score IV to V, achalasia, Zollinger-Ellison syndrome, malignant tumor, and incompetence to answer questionnaires. Forty patients were assigned by intraoperative central randomization to LMAH-C (n = 20) or LMAH-F (n = 20). Endpoints were postoperative gastroesophageal reflux, side effects, complications, and quality of life. The trial was conducted according to the guidelines for good clinical practice (Declaration of Helsinki),[10] was approved by the local ethics committee, and is registered at German Clinical Trials Register (DRKS00004492).

Preoperative assessment

Preoperatively, all patients underwent upper-gastrointestinal endoscopy to detect PEH and reflux lesions. Hiatal hernias were classified into type I (sliding), type II (pure paraesophageal), type III (mixed), and type IV (mixed with others rather than only gastric hernia sac content). Esophagitis was graded according to the Los Angeles (LA) classification.[11]

All patients were scheduled for esophageal pull-through manometry and 24-hour pH monitoring preoperatively. Esophageal pull-through manometry was available in 9 (45%) LMAH-C patients and 12 (60%) LMAH-F patients, and 24-hour pH monitoring was available in 9 (45%) LMAH-C patients and 10 (50%) LMAH-F patients. Reasons for missing pull-through manometry and 24-hour pH monitoring were patients' intolerance or unfeasibility of the examination for anatomic reasons.

Symptoms were preoperatively assessed by means of the Gastrointestinal Symptom Rating Scale (GSRS) questionnaire, with additional questions for gas bloating and dysphagia.[12] Each item was rated on a 7-point Likert scaling ranging from no discomfort (1) to very severe discomfort (7). Quality of life was assessed using the Gastrointestinal Quality of Life Index (GIQLI).[13] Preoperatively, both questionnaires were requested for patients on and off proton pump inhibitor (PPI) therapy. Additionally, the patients were screened for preoperative evidence of GERD defined in modified manner according to the criteria used by Lundell and colleagues,[14] when at least 1 of the following criteria was fulfilled: esophagitis greater than Los Angeles class A, daily need of PPIs due to reflux symptoms, or moderate to severe heartburn or acid regurgitation (GSRS reflux score > 2).

Surgical technique

The surgical technique of LMAH-C was performed as previously described in detail.[6] The operations were performed by surgeons with an experience of at least 25 laparoscopic repairs of PEH. The hernia sac was reduced after incision in the lesser omentum and the peritoneum at the hiatus. A 56F esophageal bougie was used to identify the esophagus. After mobilization of the hernia sac