Laparoscopic Mesh-augmented Hiatalplasty With Cardiophrenicopexy Versus Laparoscopic Nissen Fundoplication for the Treatment of Gastroesophageal Reflux Disease: A Double-center Randomized Controlled Trial

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OBJECTIVE
Laparoscopic mesh-augmented hiatalplasty with cardiophrenicopexy (LMAH-C) might represent an alternative treatment of gastroesophageal reflux disease (GERD) and may provide durable reflux control without fundoplication. The expected benefit is the prevention of fundoplication-related side effects. Aim of the present trial was to compare LMAH-C with laparoscopic Nissen fundoplication (LNF) in patients with GERD.

METHODS
In a double-center randomized controlled trial (RCT) patients with proven GERD were eligible and assigned by central randomization to either LMAH-C (n = 46) or LNF (n = 44). The indigestion subscore of the Gastrointestinal Symptom Rating Scale questionnaire (GSRS) indicating gas-related symptoms as possible side effects of LNF was the primary endpoint. Secondary endpoints comprised pH testing and endoscopy and other symptoms measured by the GSRS, dysphagia, and the Gastrointestinal Quality of Life Index. The follow-up period was 36 months.

RESULTS
Indigestion subscore (LMAH-C 2.9 ± 1.5 vs LNF 3.7 ± 1.6; P = 0.031) but not dysphagia (2.8 ± 1.9 vs 2.3 ± 1.7; P = 0.302) and quality of life (106.9 ± 25.5 vs 105.8 ± 24.9; P = 0.838) differed between the groups at 36 months postoperatively. Although the reflux subscore improved in both groups, it was worse in LMAH-C patients (2.5 ± 1.6 vs 1.6 ± 1.0; P = 0.004) corresponding to a treatment failure of 77.3% in LMAH-C patients and of 34.1% in LNF patients (P < 0.001).

CONCLUSIONS
LNF is more effective in the treatment of GERD than LMAH-C. Procedure-related side effects seem to exist but do not affect the quality of life. Laparoscopic fundoplication therefore remains the standard surgical treatment for GERD.

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