BRIEF REPORT

Clin Endosc 2025;58:622-624
https://doi.org/10.5946/ce.2024.284
pISSN: 2234-2400 • eISSN: 2234-2443

Open Access

CLINICAL ENDOSCOPY

Ten-year outcomes of endoscopic stapling system therapy for gastroesophageal reflux disease

Tarek G. Aridi[1], Gail McNulty[2], Glen A. Lehman[2], Mark A. Gromski[2]

[1]Department of Internal Medicine, Indiana University School of Medicine, Indianapolis, IN; [2]Division of Gastroenterology and Hepatology, Indiana University School of Medicine, Indianapolis, IN, USA

Gastroesophageal reflux disease (GERD) develops symptoms and complications due to the reflux of gastric contents into the esophagus. Left untreated, GERD can result in serious complications, including ulceration and strictures, Barrett's esophagus, and esophageal adenocarcinoma. Medical therapy is the first treatment line for mild, intermittent, and more severe and frequent GERD.[1] While proton pump inhibitors (PPIs) are the mainstay of GERD treatment, several concerns have emerged regarding their use. Approximately 30% of patients with GERD do not respond fully to PPI treatment.[2] Moreover, prolonged PPI use has been associated with serious long-term adverse events such as intestinal infections and vitamin and mineral deficiencies.[3] Alternatively, surgical techniques such as laparoscopic fundoplication have high success rates with improved GERD symptoms compared to medical therapy; however, serious side effects, particularly dysphagia, are more prevalent in patients receiving surgical treatment.[4] Other reported adverse effects associated with laparoscopic fundoplication include flatulence, bloating, diarrhea, and vomiting.[5]

Over the past two decades, minimally invasive endoscopic therapies have emerged as potentially valuable additions to the treatment of GERD. The latest guidelines from the American College of Gastroenterology recommend magnetic sphincter augmentation or transoral incisionless fundoplication as salvage therapies for refractory or milder forms of the disease.[1] The Medigus Ultrasonic Surgical Endostapler (MUSE; Medigus Ltd.) device has effectively alleviated GERD symptoms over 6 months[6] and 4 to 5 years.[7,8] This pilot study examined the long-term outcomes of this treatment over a 10-year follow-up period.

The 10-year follow-up data presented here continue the 6-month[6] and 4-year[7] findings from the prospective clinical trial of the MUSE endoscopic stapling device. The Indiana University Institutional Review Board approved this study (approval number: 1206009037). All subjects (or their legally authorized representative) were consented to participate in this research. The criteria for inclusion and a detailed description of the procedure and device used in the study are found in the initial report by Zacherl et al.[6] From 2008 to 2016, 25 patients with GERD were treated with the MUSE procedure. We examined the effectiveness of the treatment over 10 years by performing annual assessments and comparing them with baseline data. The primary outcome of this study was to evaluate the changes in GERD health-related quality of life (HRQL) scores. We obtained evaluable data, including baseline symptom assessments, from 22 treated patients. During the follow-up period, eight patients who were initially evaluable were lost to follow-up between the first and ninth years. Secondary outcomes were tracked, including changes in the GERD medication dosage (measured by omeprazole equivalents [OEs]) and the proportion of participants remaining off the daily PPI throughout the follow-up period. OE were quantified as follows: 20 OE (20 mg omeprazole/esomeprazole/pantoprazole/rabeprazole)=15 mg lansoprazole=30 mg dexlansoprazole=40 mg famotidine=300

Received: October 16, 2024 **Revised:** December 1, 2024
Accepted: December 2, 2024

Correspondence: Mark A. Gromski
Gastroenterology and Hepatology Department, Indiana University Hospital, 550 N. University Blvd, Suite 1634, Indianapolis, IN 46202, USA
E-mail: mgromski@iu.edu

mg ranitidine (note: for infrequent use of H_2-blockers and all antacid calculations: if used >once per month=5 OE). Prism ver. 9.5 (GraphPad) was used for statistical analyses and figure creation. Testing for normality and log-normality revealed that continuous data followed a nonparametric distribution. Hence, the Kruskal-Wallis test was used to analyze multiple comparisons. Statistical significance was set at $p<0.05$.

Our analysis showed that the GERD-HRQL scores showed notable improvement following the procedure. At each annual follow-up visit, the mean score, off PPIs, was significantly lower than the baseline scores. Specifically, the post-procedure GERD-HRQL scores averaged over the follow-up period's full length was 7.07±5.74, a substantial decrease from the baseline average of 31.27±6.45 (Fig. 1). Additionally, there was a significant reduction in the dosage of GERD medications as measured by annual OEs. The mean dosage after the procedure was 21.19±18.77, considerably lower than the pre-procedure baseline dosage of 47.73±21.37 (Fig. 2). Finally, we have shown that throughout the follow-up period, an average of 70.8%±10.7% of patients successfully remained off PPIs over the 10-year follow-up period (Fig. 3).

The uniqueness of our data lies in both the long-term effectiveness of the procedure in reducing GERD symptoms and the sustained reduction in the reliance on GERD medications compared with alternative endoscopic therapies. Our study showed a significant reduction in GERD-HRQL scores from baseline (by 69%–84%), with 88% of patients achieving more than a 50% reduction in scores over the 10-year follow-up period. This outcome was superior to that of the Plicator (NDO Surgical) procedure, in which only 55% of the patients achieved a similar symptom improvement at 36 months postoperatively.[9]

In conclusion, the MUSE endoscopic stapling device demon-

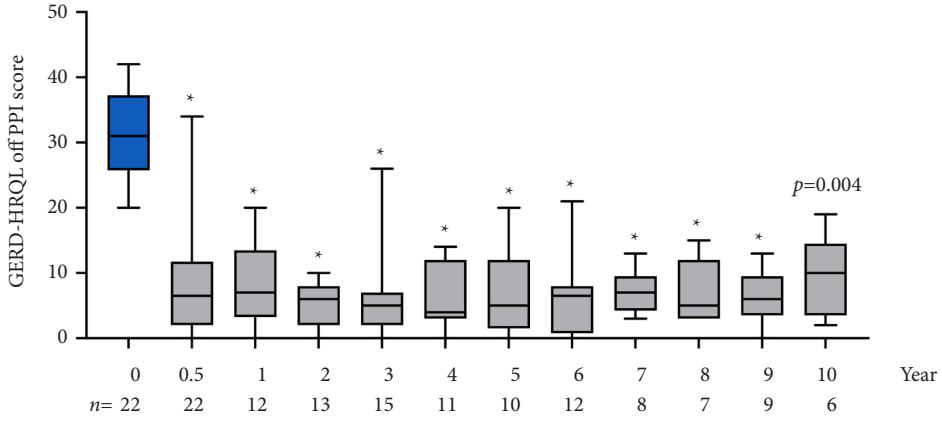

Fig. 1. Gastroesophageal reflux disease health-related quality of life (GERD-HRQL) scores, off proton pump inhibitor (PPI), at follow-up visits post-procedure compared to pre-procedure baseline. *$p<0.001$; n, no. of patients completing the HRQL scoring at each follow-up visit.

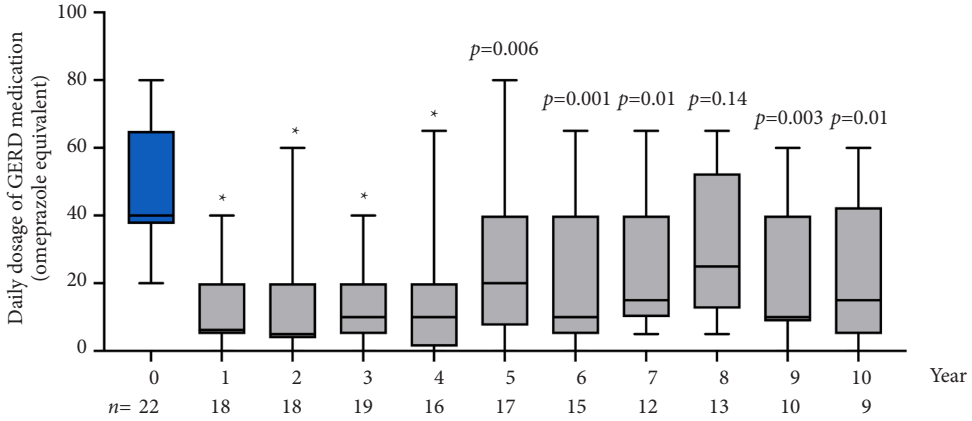

Fig. 2. Daily dose of gastroesophageal reflux disease (GERD) medications, measured in omeprazole equivalents, at follow-up visits compared to baseline preprocedural dosages. *$p<0.001$; n, no. of patients who reported GERD medication dosages at each follow-up visit.

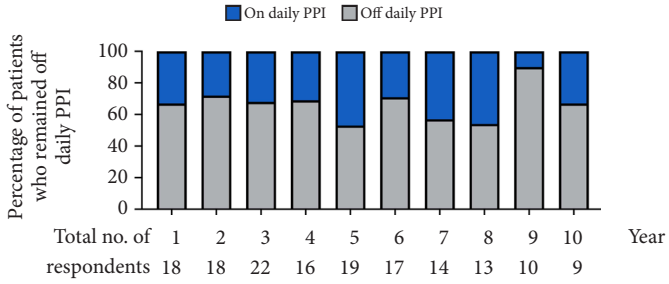

Fig. 3. Proportion of patients who remained off daily proton pump inhibitor (PPI) reported in percentage of respondents at each annual follow-up visit.

strated sustained efficacy in many patients over 10 years, with significant improvements in GERD symptom scores and reduced medication use. Despite the encouraging results, the study's limitations include the small sample size and loss of participants during follow-up, which may have affected the long-term generalizability of the findings. The MUSE system is no longer a clinically available, minimally invasive option for patients in the United States due to factors cited by the parent company, such as financial barriers, market competition, and limited clinical data supporting its effectiveness.[10] However, these data are the longest-term clinical follow-up for patients who underwent the MUSE procedure to manage GERD and provide important information to correlate with other minimally invasive endoscopic approaches to GERD.

Conflicts of Interest

The authors have no potential conflicts of interest.

Funding

Procedural study was funded by Medigus Ltd. No funding was received for the current follow-up study.

Acknowledgments

We would like to acknowledge Dr. William R. Kessler for his participation in and input into earlier studies involving this technology at our institution.

Author Contributions

Conceptualization: MAG, GAL; Data curation: GM; Formal analysis: TGA; Supervision: MAG, GAL; Writing–original draft: TGA, MAG; Writing–review & editing: all authors.

ORCID

Tarek G. Aridi https://orcid.org/0000-0002-3812-7686
Gail McNulty https://orcid.org/0000-0003-3709-4744
Glen A. Lehman https://orcid.org/0000-0002-1014-4337
Mark A. Gromski https://orcid.org/0000-0002-9035-2434

REFERENCES

1. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG clinical guideline for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2022;117:27–56.
2. Fass R. Proton-pump inhibitor therapy in patients with gastro-oesophageal reflux disease: putative mechanisms of failure. Drugs 2007;67:1521–1530.
3. Freedberg DE, Kim LS, Yang YX. The risks and benefits of long-term use of proton pump inhibitors: expert review and best practice advice from the American Gastroenterological Association. Gastroenterology 2017;152:706–715.
4. Garg SK, Gurusamy KS. Laparoscopic fundoplication surgery versus medical management for gastro-oesophageal reflux disease (GORD) in adults. Cochrane Database Syst Rev 2015;2015:CD003243.
5. Broeders JA, Roks DJ, Ahmed Ali U, et al. Laparoscopic anterior 180-degree versus nissen fundoplication for gastroesophageal reflux disease: systematic review and meta-analysis of randomized clinical trials. Ann Surg 2013;257:850–859.
6. Zacherl J, Roy-Shapira A, Bonavina L, et al. Endoscopic anterior fundoplication with the Medigus Ultrasonic Surgical Endostapler (MUSE™) for gastroesophageal reflux disease: 6-month results from a multi-center prospective trial. Surg Endosc 2015;29:220–229.
7. Kim HJ, Kwon CI, Kessler WR, et al. Long-term follow-up results of endoscopic treatment of gastroesophageal reflux disease with the MUSE™ endoscopic stapling device. Surg Endosc 2016;30:3402–3408.
8. Shen S, Yu G, Guo X, et al. The long-term efficacy of transoral incisionless fundoplication with Medigus Ultrasonic Surgical Endostapler (MUSE) for gastroesophageal reflux disease. Esophagus 2023;20:581–586.
9. Pleskow D, Rothstein R, Kozarek R, et al. Endoscopic full-thickness plication for the treatment of GERD: long-term multicenter results. Surg Endosc 2007;21:439–444.
10. Medigus Ltd. Annual report 2019 [Internet]. Medigus Ltd.; 2019 [cited 2024 Oct 16]. Available from: https://www.annualreports.com/HostedData/AnnualReportArchive/m/NASDAQ_MDGS_2019.pdf