DOI: 10.14744/cm.2024.22931
Comprehensive Medicine 2024;16(3):162-166

RESEARCH ARTICLE

The Plicator Procedure is an Alternative for the Treatment of Gastroesophageal Reflux Disease

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ABSTRACT

Objective: Endoscopic full-thickness plication of the gastric cardia using the Plicator is shown to be effective for the treatment of symptomatic gastroesophageal reflux disease (GERD). This retrospective study aimed to evaluate the Plicator procedure as an alternative to surgery.

Materials and Methods: Patients who had at least one typical reflux symptom after 6 months of PPI therapy, who were observed to have reflux findings endoscopically (LA A or B and no Barrett's metaplasia), with pathologic acid exposure in pHmetry results, hiatal hernia of <2 cm and Hill grade II and III, older than 18 years and not pregnant were included. The Plicator procedure was done endoscopically. Patients were controlled endoscopically and with pHmetry (if required) after 2 months and 1 year.

Results: The 12-month follow-up assessment was completed in 185 patients. 120 patients (65% of patients) had no reflux symptoms or endoscopic findings. 33 patients were operated on for reflux disease.

Conclusion: This is the largest published report of the Plicator procedure used for reflux patients as an alternative to surgery and 65% success rate is seen after one year. This procedure is a valid alternative for reflux patients who are unresponsive to PPIs, do not want to use long-term PPI medication due to symptom recurrence or opt for surgery.

Keywords: Endoscopic fundoplication, GERD, plicator procedure

How to cite this article: Eminoğlu L. The Plicator Procedure is an Alternative for the Treatment of Gastroesophageal Reflux Disease. CM 2024;16(3):162-166

INTRODUCTION

Gastroesophageal reflux is defined as the reflux of gastric content into the esophagus and is one of the most common digestive disorders. In contemporary literature, there are studies suggesting a 20% incidence in the general public.[1,2] Although heartburn and regurgitation are the most common symptoms, it is also associated with atypical or extraesophageal symptoms such as coughing, dysphagia, and hoarseness.[3] Quality of life is significantly reduced in GERD patients and they are exposed to complications such as ulcers, bleeding, and stricture formation in the distal esophagus. GERD patients can also develop Barrett's metaplasia which is histologically defined as the replacement of squamous epithelium with columnar epithelium. Barrett's esophagus is the most serious complication of GERD because it predisposes to esophageal adenocarcinoma, the fastest-growing cause of cancer mortality.[4,5]

If a patient has typical reflux symptoms without endoscopic examination findings this is defined as non-erosive reflux disease (NERD) and if erosions with mucosal breaks are present this is classified as erosive reflux disease (ERD). Gastroscopy can also reveal hiatal hernias which are frequently present, especially in chronic reflux patients. In addition to an endoscopic examination,pHmetry, high-resolution manometry (HRM), and impedance-pH tests can be utilized in evaluating reflux disease.[6,7]

The first line of treatment for GERD patients is pharmacological therapy, which is the use of proton pump inhibitors (PPIs). PPIs suppress the production of acid in the stomach aiming to alleviate reflux symptoms. However, a proportion of patients do not respond to PPI therapy perhaps due to ongoing non-acid regurgitation, especially in cases of lower esophageal sphincter (LES) insufficiency (i.e., hiatal hernia).[8]

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Received date: 25.04.2024
Revised date: 26.06.2024
Accepted date: 02.07.2024
Online date: 29.07.2024

Even for PPI responders, symptom recurrence and the risks of long-term PPI use and its well-studied complications are a matter of debate and it is argued whether these patients should be offered surgery.

The most definitive therapy for reflux disease is laparoscopic antireflux surgery (LARS). Nissen or Floppy Nissen procedure is the most commonly used surgical procedure and is done with a 360-degree fundoplication. In some large series long-term success as high as 80% can be observed.[9] Despite the high success rate, complications such as gas bloating syndrome and dysphagia have prompted the trial of techniques using 180- or 90-degree fundoplications to prevent such complications. But in the long run no definitive advantage was observed and Nissen technique preserved its popularity.[10,11]

New search for nonsurgical therapies without the side effects of long-term PPI use, brought endoscopic procedures under the radar. Our study was planned to evaluate the applicability and efficiency of endoscopically done full-thickness fundoplication.

MATERIALS and METHODS

The study was planned retrospectively. Patients who presented to our hospital with reflux symptoms between 2007 and 2021 were included. Patients who had reflux symptoms and were observed to have reflux findings endoscopically and pathologic acid exposure with positive pHmetry results were accepted as reflux patients. An ethics committee approval was obtained. (23/05/2023, Approval no: 230516). This study was done in accordance with Helsinki Declaration.

All patients were initially started on PPI therapy. Patients who had at least one typical reflux symptom after 4 months of medication and pathologic acid exposure on pHmetry (DeMeester score of >14.7 and symptom correlation (SI) of >50 %) or those who didinitially respond to medical therapy but had symptom recurrence or did not want to continue long-term PPI use were included in the study.

Those patients with accompanying endoscopic pathologies such as gastric ulcers, erosive gastritis were excluded. Other exclusion criteria were hiatal hernia >2 cm, presence of paraesophageal hernia, severe motility disorder of the esophagus, presence of Barrett's esophagus, esophagitis Savary Miller grade III or IV, esophageal or gastric varices and previous gastric or esophageal surgery and pregnancy.

An informed written consent was taken from all patients. The Plicator (NDO Surgical Inc. Massachusetts, USA) system was used for all the procedures (Fig. 1). The system consists of a reusable endoscopic platform, a disposable tissue retractor,a single-use pretied 2/0 polypropolene suture as implant and two expanded polytetrafluoroethlene (ePTFE) suture bolsters. The procedure is performed in an endoscopy center with the patient under general anesthesia and completed in 35 minutes on average. An upper endoscopy was performed and afterwards, the Plicator was advanced through the mouth until 10 cm below the GE junction. Then the low profile (<6 mm) endoscope was inserted through the dedicated scope channel beyond the tip of the Plicator and insufflation was done.

Following insufflation it was retroflexed to evaluate the GE junction (Fig. 2). The Plicator was retroflexed under direct vision and held directly below the GE junction. Plicator arms were opened and the tissue retractor was advanced through its dedicated channel deeply to the anterior gastric cardia to engage the muscularis level. When engaged and retracted to test the hold, the retractor was withdrawn and the arms closed while desufflation was done. Once fully closed the implant was deployed to secure the fundoplication. Insufflation was reinstated and arms were opened under vision to reveal the implants which were checked for placement and bleeding. Then the tissue retractor was removed and the Plicator was retracted through the mouth. Afterwards normal caliber gastroscope was inserted to visualize the restructured

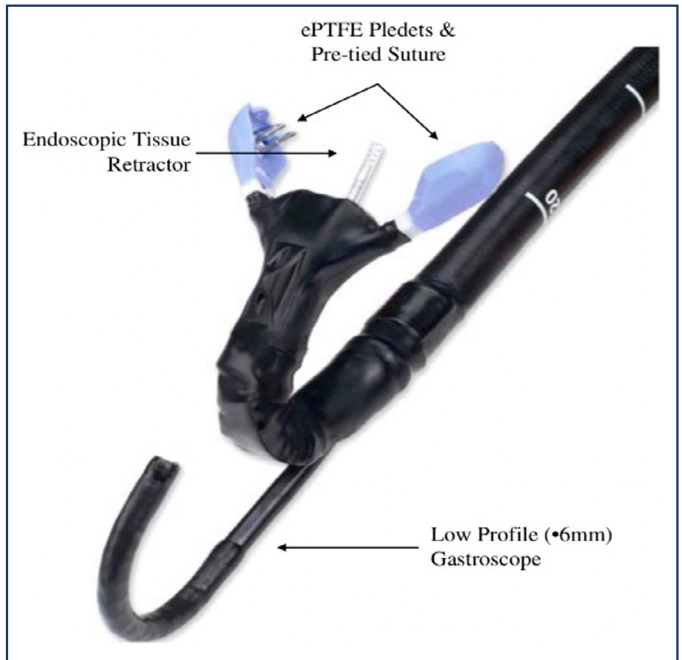

Figure 1. Plicator platform and dedicated scope (Public domain)

ePTFE: Expanded polytetrafluoroethlene

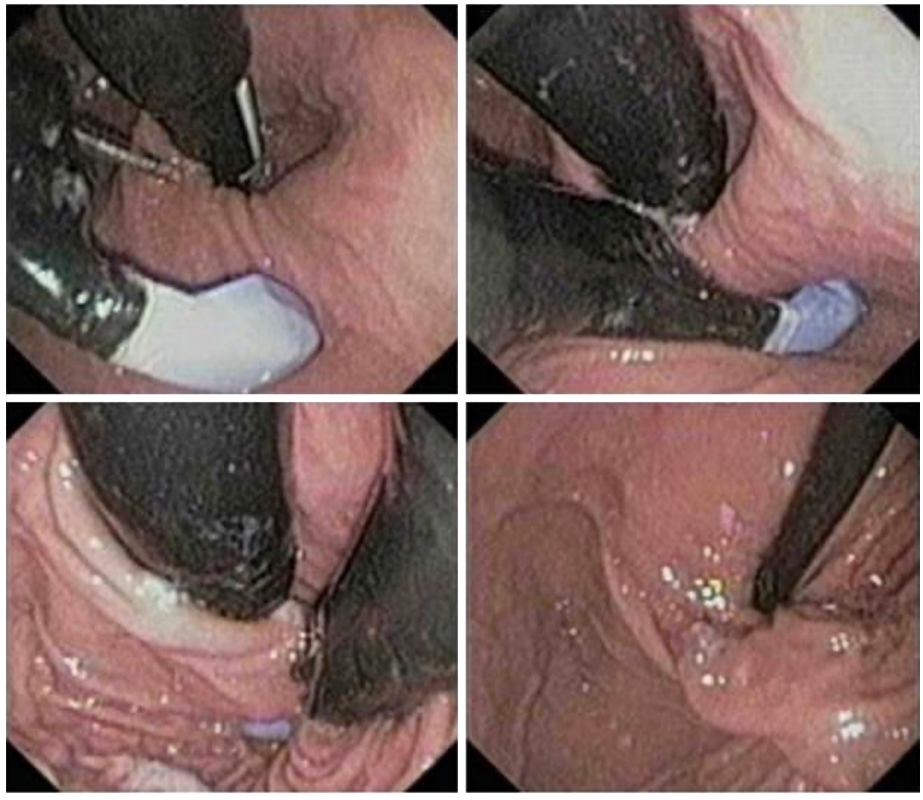

Figure 2. Deployment of pretied pledgeted suture for plication (Public domain)

GE junction. All patients received a single plication. A single dose of prophylactic antibiotic was administered.

Postoperatively, patients were observed in the hospital as outpatients for a minimum of 4 hours and discharged if no nausea or severe pain were observed. They were given PPIs for two weeks. Adaptive symptoms (nausea, vomiting, and abdominal cramps) during the first week should be closely observed and aggressively managed.

All patients were advised to consume a liquid and soft diet for the first 3 days and progress to solid food eventually. The patients were called after two months for endoscopy controls to evaluate the implants and interviewed. All patients were called again at 1 year for follow-up for an interview and endoscopy to evaluate the implants and patency of the restructured gastric valve. Esophageal pHmetry was done if the patient was symptomatic regardless of the gastroscopic findings. Results were noted.

RESULTS

900 patients with reflux symptoms were evaluated within this time period. 120 patients whose symptoms regressed did not want additional treatment and therefore were not included.595 patients were operated on. 185 patients opted for the endoscopic procedure. The procedure was explained in detail and a written consent form was obtained. Patient demographics were as follows; 120 were female and 65 were male. Median age was 45 (26–58). Median procedural time was 45 min. (30–100). No major complications were observed preoperatively or in the early postoperative period. In 48 patients minor bleeding from implant sites were observed and these stopped without further intervention. In 19 patients minor bleeding was seen from the point of tissue retractor insertion, all but 3 stopped spontaneously, in 3 patients sclerotherapy was done. All patients were discharged after 4–24 hours postoperatively no adverse effects necessitating readmission were observed in the early postoperative period. 62 patients experienced temporary dysphagia due to irritation and edema in the pharynx which resolved with medication. In 56 patients minor chest pain upon swallowing was reported by patients which also resolved spontaneously.

All patients were called for an endoscopy after 2 months for an evaluation. 185 patients were evaluated. In 6 patients disruption of the implant was observed. All other implants were observed to be in place and effective. In addition to these 6 patients

with disruption, 26 patients reported recurrence of their reflux symptoms. Medical treatment was given to these patients.

At one year postoperatively patients were endoscopically re-evaluated. In 27 patients a recurrence of endoscopic reflux esophagitis was observed. 6 patients who reported no symptoms at two-month controls were started on PPI therapy due to onset of reflux symptoms. Of the 185 patients ,120 were symptom-free and endoscopically had no reflux findings. 33 patients were operated on due to failure of the endoscopic fundoplication and onset of reflux symptoms.

DISCUSSION

Gastroesophageal reflux disease is described as the backflow of gastric contents into the esophagus. As well as being the major factor in the etiology of Barrett's esophagus and esophagogastric junction tumors; it also causes many symptoms that impair the life quality of patients. Since the standard treatment for reflux disease is not definite, conflicting approaches still exist. The guidelines for modes of treatment and indications for surgery vary among major institutions such as American Gastroenterological Society (AGA), Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), American College of Gastroenterology (ACG).[3]

Laparoscopic fundoplication is the golden standard for surgical treatment but controversy regarding which patients and when they should be operated on still continues. Choosing the right patient significantly influences the success of surgical outcome. In some patients with atypical symptoms and accompanying intestinal problems surgery may not only be unsuccessful but also create de novo problems such as dysphagia and gas bloating syndrome which are virtually nonexistent in our series.

With increasing experience, laparoscopic fundoplication can be performed with very low morbidity and mortality but is nevertheless associated with longer hospital stay and time required to return to normal activity.

Gastric and esophageal injury during surgery is very rare but still can cause fatal complications. These factors prompt the search for alternative endoscopic procedures that might be less invasive and have a lower risk profile.

The Plicator (NDO Surgical Inc. Massachusetts, USA) procedure (currently marketed as GERDx, G SURG GmHB, Germany) is the deployment of a transmural pledgeted suture at the gastroesophageal (GE) junction to bolster the gastric valve function.[10,11] The Plicator procedure has demonstrated improvements in both subjective and objective GERD treatment results in prospective and randomized controlled studies.[12–17] A previous small series demonstrated continued efficacy 3 and 5 years after treatment.[13,14] Other endoscopic antireflux procedures have been reported with similar success rates in recent publications such as the endoscopic suturing device (TIF), radiofrequency device (Stretta) and a newer technique called antireflux mucosectomy (ARMS). All these procedures seem to help control reflux with low morbidity under current information.[18]

This is the largest report of the Plicator procedure including patients who were all candidates for LARS. In earlier publications of prospective and randomized controlled trials of the Plicator procedure, the criteria for patient inclusion necessitated that patients be responsive to antisecretory therapy, as shown by analysis of baseline GERD-HRQL scores.[15,16] The limitation of our study is that we don't use a scoring system for symptom evaluation.

CONCLUSION

Not many publications exist regarding endoscopic fundoplication in the literature. Our series has a success rate of approximately 65% (symptom free and no endoscopic reflux findings). This rate is lower than laparoscopic surgery but the advantages of an endoscopic procedure should make this procedure a valuable alternative.

This study is limited because it has no control group, being done at a single treatment center, and by a single surgeon. Despite the fact that this study had no control group, similar results from surgical therapies with long-term follow up have been reported.[9] A previous (n=159) randomized, sham-controlled trial of the Plicator procedure confirmed the efficacy.[15]

As we observed the success rate go up and mortality and morbidity go down with growing laparoscopic experience; it is obvious that procedural time will shorten and success rate will increase likewise in endoscopic procedures.

Disclosures

Ethics Committee Approval: The study was approved by the University of Health Sciences Kanuni Sultan Süleyman Training and Research Hospital Clinical Research Ethics Committee (No: 230516, Date: 23/05/2023).

Conflict of Interest: No conflict of interest was declared by the authors.

Informed Consent: Written informed consent was obtained from all patients.

Use of AI for Writing Assistance: Not declared.

Financial Disclosure: The authors declared that this study received no financial support.

Peer-review: Externally peer reviewed.

REFERENCES

1. Dean BB, Crawley JA, Schmitt CM, Wong J, Ofman JJ. The burden of illness of gastro-oesophageal reflux disease: impact on work productivity. Aliment Pharmacol Ther 2003;17:1309–17. [CrossRef]
2. Frank L, Kleinman L, Ganoczy D, McQuaid K, Sloan S, Eggleston A, et al. Upper gastrointestinal symptoms in North America: prevalence and relationship to healthcare utilization and quality of life. Dig Dis Sci 2003;45:809–18. [CrossRef]
3. Sandler RS, Everhart JE, Donowitz M, Adams E, Cronin K, Goodman C, et al. The burden of selected digestive diseases in the United States. Gastroenterology 2002;122:1500–1. [CrossRef]
4. Fass R, Ofman JJ. Gastroesophageal reflux disease: should we adopt a new conceptual framework? Am J Gastroenterol 2002;97:1901–9. [CrossRef]
5. Poelmans J, Tack J. Extraoesophageal manifestations of gastro-oesophageal reflux. Gut 2005;54:1492–9. [CrossRef]
6. Ruigomez A, Garcia Rodriguez LA, Wallander MA, Johansson S, Graffner H, Dent J. Natural history of gastro-oesophageal reflux disease diagnosed in general practice. Aliment Pharmacol Ther 2004;20:751–60. [CrossRef]
7. Wiklund I. Review of the quality of life and burden of illness in gastroesophageal reflux disease. Dig Dis 2004;22:108–14. [CrossRef]
8. Dent J, El-Serag HB, Wallander MA, Johansson S. Epidemiology of gastro-oesophageal reflux disease: a systematic review. Gut 2005;54:710–7. [CrossRef]
9. Spechler SJ, Lee E, Ahnen D, Goyal RK, Hirano I, Ramirez F, et al. Long-term outcome of medical and surgical therapies for gastroesophageal reflux disease: follow-up of a randomized controlled trial. JAMA 2005;285:2331–8. [CrossRef]
10. Cadiere GB, Rajan A, Germay O, Jimpens J. Endoluminal fundoplication by a transoral device for the treatment of GERD: a feasibility study. Surg Endosc 2008;22:333–42. [CrossRef]
11. Birk J, Pruitt R, Haber G, Raijman I, Baluyut A, Meiselman M, et al. The Plicator procedure for the treatment of gastroesophageal reflux disease: a registry study. Surg Endosc 2009;23:423–31. [CrossRef]
12. Pleskow D, Rothstein R, Lo S, Hawes R, Kozarek R, Haber G, et al. Endoscopic full-thickness plication for the treatment of GERD: a multicenter trial. Gastrointest Endosc 2004;59:163–71. [CrossRef]
13. Schwartz MP, Wellink H, Gooszen HG, Conchillo JM, Samsom M, Smout A. Endoscopic gastroplication for the treatment of gastro-oesophageal reflux disease: a randomised, sham-controlled trial. Gut 2007;56:20–8. [CrossRef]
14. Deviere J, Costamagna G, Neuhaus H, Voderholzer W, Louis H, Tringali A, et al. Nonresorbable copolymer implantation for gastroesophageal reflux disease: a randomized sham-controlled multicenter trial. Gastroenterology 2005;128:532–40. [CrossRef]
15. Pleskow D, Rothstein R, Lo S, Hawes R, Kozarek R, Haber G, et al. Endoscopic full-thickness plication for GERD: 12-month follow-up for the North American openlabel trial. Gastrointest Endosc 2005;61:643–9. [CrossRef]
16. Freston JW, Triadofilopoulos G. Review article: approaches to the long-term management of adults with GERD-proton pump inhibitor therapy, laparoscopic fundoplication, or endoscopic therapy? Aliment Pharmacol Ther 2004;19(Suppl 1):35–42. [CrossRef]
17. Weitzendorfer M, Spaun GO, Antoniou SA, Witzel K, Emmanuel K, Koch OO. Clinical feasibility of a new full-thickness endoscopic plication device (GERDx™) for patients with ERD: results of a prospective trial. Surg Endosc 2018;32:2541–9. [CrossRef]
18. Richardson WS, Gorham JK, Neal N, Fanelli RD. Endoscopic treatment of gastroesophageal reflux disease. Adv Surg 2022;56:205–27. [CrossRef]