EDITORIAL

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CLINICAL ENDOSCOPY

Long-term efficacy of endoscopic radiofrequency Stretta therapy for patients with refractory gastroesophageal reflux disease

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See "Endoscopic radiofrequency Stretta therapy reduces proton pump inhibitor dependency and the need for anti-reflux surgery for refractory gastroesophageal reflux disease" by Abraham Joel, Alakh Konjengbam, Yirupaiahgari Viswanath, et al., Clin Endosc 2024;57:58–64.

Gastroesophageal reflux disease (GERD) occurs when the reflux of stomach contents causes troublesome symptoms and/or complications and is considered as a common gastrointestinal disease worldwide. Although the prevalence of GERD in Eastern Asia is relatively low compared to that in the United States and other countries, a systematic analysis of the Global Burden of Disease Study reported that the mean estimates of age-standardized GERD prevalence in 2017 ranged from 4,408 to 14,035 per 100,000 population.[1]

Acid suppression is a fundamental treatment strategy for GERD. Proton pump inhibitors (PPIs) and potassium-competitive acid blockers are the mainstay medical treatments for GERD. However, a systematic review of observational studies revealed that 45.0% of patients with GERD in primary care or community-based studies had persistent reflux symptoms despite taking PPIs.[2] These patients are usually defined as those with refractory GERD.[2] The treatment of refractory GERD is challenging in clinical practice. To treat refractory GERD, physicians may prescribe additional medications (such as prokinetics, baclofen, and alginate) or recommend anti-reflux surgery as an alternative to PPI maintenance therapy. Endoscopic therapies are also recognized as treatment and may serve as a bridge between medical treatment and surgical fundoplication.[3]

Endoscopic therapies can be categorized into three: (1) transoral incisionless fundoplication using endoscopic plication devices, (2) radiofrequency energy delivery, and (3) reinforcement of the lower esophageal sphincter (LES).[4] Among them, the Stretta therapy applies the method of radiofrequency energy delivery system approach, which enforces the LES and gastric cardia muscles with four needle electrodes that extend out from a balloon catheter into the muscle at six levels across the gastroesophageal junction, leading to improved reflux symptoms. The Stretta system was approved by the Food and Drug Administration for the endoscopic therapy of GERD in 2000. Since then, more than 25,000 procedures have been conducted.[5,6]

Multiple randomized controlled trials (RCTs) and systematic reviews have investigated the efficacy of Stretta therapy. A meta-analysis (28 studies [four RCTs, 23 cohort studies, and one registry], n=2,468) found that Stretta therapy could improve health-related quality of life (HRQOL) and heartburn (both p<0.001). In terms of the objective metrics, the Stretta therapy

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decreased the incidence of erosive esophagitis and esophageal acid exposure (both $p<0.001$). In addition, 51% of patients taking PPIs at baseline discontinued PPIs at follow-up ($p<0.001$).[7] However, another meta-analysis study (four RCTs, $n=153$) reported no significant differences in the physiologic parameters, such as the mean percent of time with pH <4 in 24 hours, LES pressure, elimination of PPIs, or HRQOL between the Stretta therapy and sham or PPI use.[8] A few studies have evaluated the long-term efficacies of the Stretta therapy. Noar et al.[9] conducted a 10-year, open-label, prospective study ($n=217$) to investigate the long-term efficacy, safety, and durability of response to the Stretta therapy. At 10 years, 72% of the patients achieved normalization of HRQOL, 64% of patients showed a ≥50% reduction in PPIs, and 41% of patients showed elimination of PPIs.

In this issue of *Clinical Endoscopy*, Joel et al.[10] reported the clinical outcomes of the Stretta therapy in patients with refractory GERD. From October 2014 to June 2022, 195 patients underwent the Stretta therapy at a tertiary center in the United Kingdom. Of these, 144 (73.8%) had a PPI-free period (PFP). After a median follow-up of 55 months, 66 patients (45.8%) had discontinued PPI. PFP and age had a statistically significant negative correlation ($p=0.007$). However, PFP and sex showed no statistically significant correlation ($p=0.96$). In a subgroup analysis, the authors divided the patients into younger and older groups based on their age of 55 years. There was a significant difference in PFP between younger and older men. However, there was no significant difference in PFP between younger and older women. Therefore, they suggested that the Stretta therapy is a suitable option for treating refractory GERD, particularly in younger patients.

This was a long-term follow-up study evaluating the efficacy of the Stretta therapy, with a median follow-up of 55 months (interquartile range, 42–67 months). In addition, it suggests that there may be differences in the response to the Stretta therapy based on the age and sex. However, this study had some limitations. It was a single-arm study, and 26.2% of the patients were lost to follow-up. Recently, there has been growing interest in the sex differences in clinical medicine. A more in-depth discussion on the reasons for sex differences observed in this study may be warranted.

The Stretta therapy was described in the 2020 Seoul Consensus on the management of GERD. Although there was a recommendation for anti-reflux surgery, there was no specific recommendation for endoscopic therapy.[3] A recent American College of Gastroenterology clinical guideline for the management of GERD states that the Stretta therapy cannot be recommended as an alternative to medical treatment or anti-reflux surgery since the results of the Stretta studies are inconsistent and highly variable.[11] However, the quality of evidence is low, and the strength of recommendation is conditional. Therefore, large-scale, well-designed studies are required in the future to demonstrate the efficacy of the Stretta therapy in GERD, including refractory GERD.

Conflicts of Interest

Sung Eun Kim is currently serving as a KSGE Publication Committee member in *Clinical Endoscopy*; however, she was not involved in the peer reviewer selection, evaluation, or decision process of this article.

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