Journal of Clinical and Nursing Research, 2025, Volume 9, Issue 5
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Clinical Advances in Esophageal Anti-reflux Stents

Yongqi Dang[1], Fende Liu[2], Aiai Yan[1], Caifeng Xu[3], Xu Yang[1], Yu Cai[2]*

[1]School of General Medicine, Xi'an Medical University, Xi'an 710021, Shaanxi, China
[2]Cardiovascular Surgery, The First Affiliated Hospital of Xi'an Medical University, Xi'an 710061, Shaanxi, China
[3]Pharmaceutical Sciences of Xi'an Medical University, Xi'an 710021, Shaanxi, China

**Corresponding author:* Yu Cai, caiyu_1985@163.com

Copyright: © 2025 Author(s). This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY 4.0), permitting distribution and reproduction in any medium, provided the original work is cited.

Abstract: As an emerging treatment, esophageal anti-reflux stent has gradually become the palliative treatment of choice for many digestive diseases due to its features of low trauma, high safety, and conformity to the physiological and anatomical structure of the esophagus. This study presents a review of the latest clinical progress of esophageal anti-reflux stents to provide theoretical references for subsequent studies.

Keywords: Esophageal anti-reflux stent; Esophageal cancer; Gastroesophageal reflux; Palliative care

Online publication: June 3, 2025

1. Introduction

With the improvement of national living standards, the incidence of digestive diseases is rising, and the esophageal anti-reflux stent has also received widespread attention as an emerging therapeutic means [1, 2]. The stent is mainly used to relieve stenosis and obstruction at the lower esophagus and gastroesophageal conjunction and effectively prevent complications such as reflux, and can be widely used in malignant stenosis of the esophagogastric conjunction, pancreatic achalasia, gastroesophageal reflux disease, esophageal fistula, esophageal perforation, esophageal diverticulum, and esophageal dysfunction and other diseases [3–5]. It has gradually become the preferred palliative treatment for some gastrointestinal diseases because of its characteristics of low trauma, high safety, and conformity to the physiological anatomy of the esophagus. This study reviews the latest progress of esophageal anti-reflux stents, introducing their mechanism of action, material selection, and clinical application. Meanwhile, it looks forward to the development direction and application value of this field, and provides a reference for further research on esophageal anti-reflux stents.

2. Overview

The esophageal anti-reflux stent is used to reduce the incidence of reflux events by placing a structurally specific stent at the gastroesophageal junction to form a physical barrier that enhances the pressure on the lower esophageal sphincter and prevents gastric contents from refluxing into the esophagus. The principle is similar to that of fundoplication in traditional surgery, but it is minimally invasive and has the clinical advantage of significantly reducing the risk of treatment and shortening the postoperative recovery period [6–8].

The structure of esophageal anti-reflux stents is generally consistent, typically consisting of two main components: the stent body and an anti-reflux valve. The valve, added to the distal end of a traditional esophageal stent, helps prevent gastric content reflux while maintaining esophageal patency. Currently, anti-reflux stent structures mainly include windward pocket valve stents, tricuspid valve stents, and cardiac umbrella valve stents [9]. Most of the currently available stents are retrievable or adjustable, and they are designed by pulling a lasso cord attached to one or both ends, or by using a dedicated retrieval device before complete endothelialization.

The stent surface can be fully coated, partially coated or bare stent. Uncoated stents are poorly histocompatible, and their long-term placement can stimulate the normal mucosal tissue of the esophagus or tumor tissue proliferation into the stent mesh, leading to restenosis of the stent [10]. Commonly used coating materials for coated esophageal stents include polyester, silicone, and polyethylene [11]. The surface of partially or fully coated esophageal stents becomes smooth, and they are easily displaced or even dislodged after placement [12]. Currently, the most widely used clinical stent is the coated nickel-titanium metal stent, which has the advantages of good histocompatibility, morphologic memory, and moderate elasticity. Coated SEMS is the stent of choice for the treatment of malignant lesions in the esophagus, and its main advantage is that it can avoid inward tumor growth [13, 14].

3. Esophageal anti-reflux stents in esophageal cancer

Esophageal cancer (EC) is the eighth most common type of cancer in the world, and its mortality rate is the sixth most common malignant tumor worldwide [15]. Progressive dysphagia due to malignant obstruction of the esophagus is the main symptom of advanced esophageal cancer, and more than half of the patients who seek medical attention for dysphagia have already progressed to advanced esophageal cancer, losing the opportunity for radical surgical resection [16]. Among the various treatments for middle- and late-stage esophageal cancer, esophageal stent placement has the unique advantage of instantly relieving dysphagia, and it is a safe and effective method to improve the nutritional status of patients and enhance their quality of life [17]. In recent years, with the improvement of manufacturing level as well as material science technology, a variety of anti-reflux stents have been developed, and randomized controlled trials have been conducted to evaluate various types of esophageal anti-reflux stents.

Sasso *et al.* included a total of 10 randomized clinical trials involving 467 patients with esophageal cancer, in which self-expanding metallic stents with valve (SEMS-V) were placed in the study group (234 patients) and non-valve self-expanding metallic stents (SEMS-NV) were placed in the control group (233 patients) [1]. A self-expanding metallic stent with valve (SEMS-V) was inserted into 234 of these patients. The results showed that both groups had safety and efficacy in esophageal cancer remission, and there was no statistically significant difference in the incidence of GERD, dysphagia remission, technical success, stent displacement, and obstruction after stenting. Dua *et al.* conducted a double-blind controlled study involving 60 patients with malignant dysphagia, in which self-expandable metal stents (SEMS) and SEMS with tricuspid anti-reflux valves

(SEMS-V) were implanted at the gastroesophageal junction. The results showed that both groups demonstrated comparable outcomes in terms of dysphagia scores at 2 weeks and GERD-HRQL scores at 4 weeks [18]. After 24 weeks of follow-up, no valve-related complications were observed in the SEMS-V group, and there was no significant difference in GERD symptom scores between the two groups, suggesting that the antireflux valve may have functional limitations, and not ruling out the possibility that the use of proton pump inhibitors may have an interfering effect on GERD assessment. Although antireflux stents theoretically prevent reflux, the studies by Sasso *et al.* and Dua *et al.* failed to confirm the clinical benefits of esophageal antireflux stents.

Shim *et al.* randomly assigned 36 patients with gastroesophageal junction cancer to placement of newly designed self-expanding metal stents with anti-reflux mechanisms or standard open stents [19]. Technical success, clinical efficacy, dysphagia scores, reflux symptoms, and complications were assessed one week after the procedure with 24-hour ambulatory esophageal pH monitoring. Studies have shown that newly designed anti-reflux stents are effective in relieving dysphagia caused by malignant cancers at the gastroesophageal junction, as well as being more effective than currently available anti-reflux stents in preventing gastroesophageal reflux. A Belgian study used the Niti-S double-coated anti-reflux stent [3]. The study included 29 patients with malignant esophageal stenosis who underwent Niti-S double-coated anti-reflux stent placement (30 stents in total). The results of this study confirmed the significant efficacy of the stents on dysphagia and reflux symptoms, with no stent migration observed, a low incidence of tissue overgrowth, and no serious complications such as perforation, fistula, or food impaction. This study suggests that the Niti-S esophageal dual-coverage anti-reflux stent is a safe and effective treatment option for malignant esophageal strictures. However, the results of this study are small, but larger multicenter studies are needed to further validate its long-term efficacy.

4. Esophageal anti-reflux stents in pancreatic dysplasia

Pancreatic achalasia is a rare primary esophageal dyskinesia characterized by loss of function of the distal esophageal and lower sphincter plexus cells, most commonly seen in the elderly population [20]. Its pathogenesis, in addition to histologic abnormalities, may be related to molecular inflammation and genetic factors, and its clinical manifestations include dysphagia, regurgitation, chest pain, and weight loss. Currently, treatment options for cardia dysphagia focus on lowering the resting pressure of the lower esophageal sphincter to help empty the esophagus and relieve symptoms. Therapeutic measures include botulinum toxin injections, endoscopic balloon dilatation or transoral endoscopic myotomy (POEM) as well as performing Heller myotomy and laparoscopic surgery [21]. Stent placement has become an important alternative for refractory or inoperable patients. Stent placement has minimally invasive and rapid results, a reversible design, and flexible therapeutic properties, which can effectively relieve dysphagia, reduce reflux, and improve patients' quality of life.

As early as 1996, De Palma *et al.* demonstrated the short-term efficacy and safety of removable self-expanding metal stents for the treatment of cardia laxity [22]. In 2009, Tang *et al.* placed a perimetabolic anti-reflux stent in 20 patients with cardia laxity, and all of them showed significant improvement in their dysphagia, with only a few of them experiencing transient chest pain or a foreign-body sensation, and no recurrence after a follow-up period of 8 to 30 months [23]. No recurrence was observed after 8–30 months of follow-up, which strongly proved that the treatment of cardia dysphagia with periosteal anti-reflux esophageal stent has the characteristics of convenient operation, few complications, safety, and good near-term therapeutic efficacy. However, because of its unknown pathogenesis and mechanism, the long-term efficacy and stent placement time

need to be further observed.

A retrospective study involving 166 patients with achalasia of the cardia compared the outcomes of fully coated anti-reflux metallic stent (FCARMS) implantation and peroral endoscopic myotomy (POEM) [4]. The results showed that FCARMS was comparable to POEM in short-term efficacy (< 6 months) and was more cost-effective. However, POEM demonstrated significant long-term advantages (> 2 years), particularly in patients evaluated with high-resolution manometry. However, long-term (> 2 years) POEM had a significant advantage, especially in high-resolution manometry II (HRM II) patients. This result suggests the need to individualize the choice of stenting according to patient type, economic conditions, and treatment expectations. The results suggest that stenting is a cost-effective and safe therapeutic option for cardia dystrophy.

5. Application of esophageal anti-reflux stents in gastroesophageal reflux disease

Gastroesophageal reflux disease (GERD) is a common disease of the digestive system in which gastric contents (including gastric acid and digestive enzymes) reflux into the esophagus, causing uncomfortable symptoms or complications [24]. GERD is widely prevalent worldwide, and according to the statistics, the global prevalence of GERD ranges from 2.5% to 51.2%, with an average prevalence of 14.8%. According to statistics, the global prevalence of GERD ranges from 2.5% to 51.2%, with an average prevalence of 14.8% [25]. The main clinical symptoms are heartburn, reflux, and atypical symptoms such as chest pain, dysphagia, cough, and recurrent pneumonia, as well as common complications such as esophagitis, Barrett's esophagus, and esophageal stricture [26]. Its pathogenesis is mainly due to esophageal sphincter (LES) dysfunction, decreased esophageal clearance, delayed gastric emptying, and weakened esophageal mucosal defense mechanism. The current treatment is mainly to reduce gastric acid secretion, promote the healing of esophageal mucosa, enhance the function of the lower esophageal sphincter by minimally invasive means, reduce reflux, and rebuild the anti-reflux barrier through surgery [27]. Anti-reflux stents have become a novel option for some patients who are ineffective on medications and lifestyle modifications and cannot tolerate surgery on their own. The use of esophageal anti-reflux stents in GRED has only been reported in case or small-sample studies. Hirdes *et al.* first reported the placement of a self-designed anti-reflux system (RCS) inside the stent in 10 patients with gastroesophageal reflux despite esophageal stenting through the LES and in one patient with severe bile reflux after esophageal jejunostomy and conducted a prospective follow-up study [28]. The results showed that placement of the RCS was technically feasible and safe, and that the RCS hardly migrated when the appropriate diameter was selected, while the patients experienced a significant reduction in reflux symptoms. However, the study had a small number of patients, a nonrandomized design, and lacked pH measurements. Its clinical efficacy should be evaluated in a controlled trial. Qiu *et al.* reported a study of symptomatic follow-up of 28 patients with CZES-type anti-reflux esophageal stents who had been followed up for more than two years [29]. The results showed that the CZES-type anti-reflux esophageal stent was effective in preventing acid reflux and maintained good physical properties over a long period of time.

6. Conclusion

This study introduces the clinical application of esophageal anti-reflux stents in esophageal cancer, pancreatic achalasia, and gastroesophageal reflux disease by reviewing the relevant literature on esophageal anti-reflux stents. Anti-reflux stents have not yet been applied in large scale in clinical practice. However, as an emerging therapeutic

means, they have shown good anti-reflux effect and clinical application prospect. More prospective clinical trials are needed to validate the anti-reflux stent in terms of material selection, design of anti-reflux structure, exploration of indications, long-term efficacy, complication control, and timing of clinical application. Through the continuous improvement of stent materials and design, as well as the combination of individualized treatment and combined treatment strategies, it is expected that the therapeutic effect of esophageal anti-reflux stents will be further improved in the future, and they may become the first-line treatment modality for the treatment of middle- and late-stage esophageal cancer, pancreatic achalasia, gastroesophageal reflux disease, and other diseases.

Funding

National College Students' Innovative Entrepreneurial Training Plan Program Funded Project (Project No.: 2024118400010)

Disclosure statement

The authors declare no conflict of interest.

References

[1] Sasso JGRJ, de Moura DTH, Proenca IM, et al., 2022, Anti-Reflux Versus Conventional Self-Expanding Metal Stents in the Palliation of Esophageal Cancer: A Systematic Review and Meta-Analysis. Endosc Int Open, 10(10): E1406–E1416.

[2] Pandit S, Samant H, Morris J, et al., 2019, Efficacy and Safety of Standard and Anti-Reflux Self-Expanding Metal Stents: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. World J Gastrointest Endosc, 11(4): 271–280.

[3] Van Overbeke L, van Dongen J, 2022, Niti-S Esophageal Covered Stent (Double Anti-Reflux Type): An Observational Patient Registry/Post-Market Clinical Follow-Up Study. Acta Gastroenterol Belg, 85(3): 493–497.

[4] Tang YF, Jin P, Tao YR, et al., 2022, Comparison of Fully Coated Anti-Reflux Metal Stenting and Per-Oral Endoscopic Myotomy in Patients With Achalasia: A Propensity Score-Matched Retrospective Study. BMC Gastroenterol, 22(1): 253.

[5] Bi Y, Yi M, Yu Z, et al., 2020, Covered Metallic Stent for the Treatment of Malignant Esophageal Fistula Combined With Stricture. BMC Gastroenterol, 20(1): 248. doi:10.1186/s12876-020-01398-6

[6] Tata MD, Mahazir NQA, Keat OW, et al., 2022, Impact of a New Conceptualized Anti-Reflux Trumpet Stent on the Quality of Life of Patients With Advanced Carcinoma of the Cardio-Esophageal Junction. Ghana Med J, 56(2): 95–99. doi:10.4314/gmj.v56i2.6

[7] Conio M, Savarese MF, Filiberti RA, et al., 2021, Palliation of Malignant Esophageal Obstruction Using an Anti-Migration Self-Expandable Metal Stent: Results of a Prospective Multicenter Study. Clin Res Hepatol Gastroenterol, 45(3): 101683. doi:10.1016/j.clinre.2021.10168 3

[8] Fuccio L, Hassan C, Frazzoni L, et al., 2016, Clinical Outcomes Following Stent Placement in Refractory Benign Esophageal Stricture: A Systematic Review and Meta-Analysis. Endoscopy, 48(2): 141–148. doi:10.1055/s-0034-1393331

[9] Ma L, Tang X, Fan Z, 2012, Recent Advances in Anti-Reflux Stents for the Esophagus. China Medical Device Information, 18(10): 12–16, 71.

[10] Li B, Li B, Li L, et al., 2020, Progress in the Clinical Application of Esophageal Stents in Esophageal Diseases. Continuing Medical Education, 34(1): 74–76.

[11] Katsanos K, Sabharwal T, Adam A, 2010, Stenting of the Upper Gastrointestinal Tract: Current Status. Cardiovasc Intervent Radiol, 33(4): 690–705.

[12] Yang Z, Wu Q, Wang F, et al., 2013, A Systematic Review and Meta-Analysis of Randomized Trials and Prospective Studies Comparing Covered and Bare Self-Expandable Metal Stents for the Treatment of Malignant Obstruction in the Digestive Tract. Int J Med Sci, 10(7): 825–835.

[13] Sabharwal T, Morales JP, Irani FG, Adam A, 2005, Quality Improvement Guidelines for Placement of Esophageal Stents. Cardiovasc Intervent Radiol, 28(3): 284–288.

[14] Sabharwal T, Morales JP, Salter R, et al., 2005, Esophageal Cancer: Self-Expanding Metallic Stents. Abdom Imaging, 30(4): 456–464.

[15] Uhlenhopp DJ, Then EO, Sunkara T, et al., 2020, Epidemiology of Esophageal Cancer: Update in Global Trends, Etiology and Risk Factors. Clin J Gastroenterol, 13(6): 1010–1021.

[16] Halpern AL, McCarter MD, 2019, Palliative Management of Gastric and Esophageal Cancer. Surg Clin North Am, 99(3): 555–569.

[17] Expert Group, 2020, Expert Consensus on the Clinical Application of Esophageal Cancer Stent Placement. Chinese Journal of Interventional Radiology (Electronic Edition), 8(4): 291–296.

[18] Dua KS, DeWitt JM, Kessler WR, et al., 2019, A Phase III, Multicenter, Prospective, Single-Blinded, Noninferiority, Randomized Controlled Trial on the Performance of a Novel Esophageal Stent With an Antireflux Valve. Gastrointest Endosc, 90(1): 64–74.e3.

[19] Shim CS, Jung IS, Cheon YK, et al., 2005, Management of Malignant Stricture of the Esophagogastric Junction With a Newly Designed Self-Expanding Metal Stent With an Antireflux Mechanism. Endoscopy, 37(4): 335–339.

[20] Savarino E, Bhatia S, Roman S, et al., 2022, Achalasia. Nat Rev Dis Primers, 8(1): 28. doi:10.1038/s41572-022-00356-8

[21] Li MY, Wang QH, Chen RP, et al., 2023, Pathogenesis, Clinical Manifestations, Diagnosis, and Treatment Progress of Achalasia of Cardia. World J Clin Cases, 11(8): 1741–1752.

[22] De Palma GD, Catanzano C, 1998, Removable Self-Expanding Metal Stents: A Pilot Study for Treatment of Achalasia of the Esophagus. Endoscopy, 30(8): S95–S96.

[23] Tang S, Yuan H, Wang M, et al., 2009, Treatment of Achalasia With Coated Anti-Reflux Esophageal Stent. Minimally Invasive Medicine, 4(4): 365–366.

[24] Katzka DA, Kahrilas PJ, 2020, Advances in the Diagnosis and Management of Gastroesophageal Reflux Disease. BMJ, 371: m3786.

[25] Eusebi LH, Ratnakumaran R, Yuan Y, et al., 2018, Global Prevalence of, and Risk Factors for, Gastro-Oesophageal Reflux Symptoms: A Meta-Analysis. Gut, 67(3): 430–440.

[26] Dunbar KB, 2024, Gastroesophageal Reflux Disease. Ann Intern Med, 177(8): ITC113–ITC128. doi:10. 7326/AITC202408200

[27] Yodice M, Mignucci A, Shah V, et al., 2021, Preoperative Physiological Esophageal Assessment for Anti-Reflux Surgery: A Guide for Surgeons on High-Resolution Manometry and pH Testing. World J Gastroenterol, 27(16): 1751–1769.

[28] Hirdes MM, Vleggaar FP, Laasch HU, et al., 2012, Technical Feasibility and Safety of a New, Implantable Reflux Control System to Prevent Gastroesophageal Reflux in Patients With Stents Placed Through the Lower Esophageal

Sphincter. Gastrointest Endosc, 75(1): 174–178.

[29] Qiu X, Jiao F, Liu Z, 2003, Long-Term Efficacy of CZES Anti-Reflux Esophageal Stent and Study on the Function of Anti-Reflux Valve. China Journal of Endoscopy, 9(1): 79–80, 82.

Publisher's note

Bio-Byword Scientific Publishing remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.