

# Tubular fully covered self-expandable metallic stents for endoscopic ultrasound-guided gastrojejunostomy: moving forward or taking a step back?

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See “Endoscopic ultrasound-guided gastrojejunostomy with a direct technique without previous intestinal filling using a tubular fully covered self-expandable metallic stent” Hakan Şentürk, İbrahim Hakkı Köker, Koray Koçhan, et al., Clin Endosc 2024;57:209–216.

Endoscopic ultrasound-guided gastroenterostomy (EUS-GE) has recently gained momentum as an alternative to enteral stenting and surgical gastroenterostomy (GE) for the management of gastric outlet obstruction (GOO). Despite variations in techniques and approaches (direct EUS-GE, balloon-assisted EUS-GE, and EUS-guided double-balloon-occluded gastrojejunostomy bypass), EUS-GE bypasses any anatomical obstruction (benign or malignant) by directly bridging the stomach to the small bowel. Lumen-apposing metallic stents (LAMS), with their unique dumbbell design, wider biflanges, and variable lengths and diameters, aim to provide the secure anchoring system necessary for creating such anastomoses. Cautery-tip enhancement LAMS (CE-LAMS) served in streamlining EUS-GE by facilitating a one-step “free-hand” insertion rendering the procedure more efficient and economical. In a systematic review, the technical and clinical success rates of EUS-GE were

93% and 90%, respectively, with 5.6% serious adverse events (peritonitis, perforation, and bleeding) and 11.5% re-intervention rates.<sup>1</sup> Nonetheless, stent misdeployment with LAMS occurs in 9.85% of cases and remains a salient obstacle to its widespread adoption.<sup>2</sup> Furthermore, technical outcomes evaluated in a multicenter retrospective study revealed that they were not affected by the presence or absence of prior interventions, altered anatomy, or the use of LAMS with or without cautery.<sup>3</sup> An optimal interluminal distance of 19 mm is a predictor of technical success, whereas the presence of ascites is a warning of failure.<sup>4</sup> Consequently, the quest for an “ideal stent” (affordable, accessible, effective, safe, easy to deploy, migration proof) persists irrespective of whether the newly United States (US) Food and Drug Administration cleared double-balloon device- or other future devices for that matter, gain popularity in EUS-GE or not.

In their retrospective pilot study involving 21 patients with GOO (19/21 malignant), Şentürk et al.<sup>5</sup> explored the technical and clinical outcomes of EUS-GE using a readily available duodenal stent (20 mm×80 mm fully-covered self-expandable metallic stents [FCSEMS], HILZO Stent; BCM Co. Ltd.). The jejunum, distal to the ligament of Treitz, was fluoroscopically accessed using a 19 G needle and the guidewire was advanced. In 8/21 patients, more than one puncture was required to obtain enteric access. No fluid distension was attempted. After

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the tract was dilated with a 6 Fr cystotome or a 4 mm biliary balloon (6/21 cases), the FCSEMS was deployed and its lumen was dilated to 15 mm (because in one case, a 20 mm dilation resulted in stent migration). The median procedure time was 33 minutes (range, 23–55 minutes), with a technical success rate of 100% and a clinical success rate of 90.5% (two patients with gastric cancer remained symptomatic with an inability to advance their diet beyond liquids). The median survival time was 118 (range, 41–194) days.

FCSEMS of various sizes have been previously employed in the creation of anastomoses, such as EUS-guided hepaticogastrostomy and choledochoduodenostomy. In addition, FCSEMS have served as a salvage therapy for type II EUS-GE LAMS misdeployment.<sup>2</sup> The expanded use of FCSEMS for the primary purpose of EUS-GE is novel. When compared to the commonly utilized CE-LAMS (AXIOS Stent, Boston-Scientific), the dimensions of the Hilzo Stents are nearly identical, except for the saddle length (1 cm vs. 5 cm) and outer diameter of the delivery catheter (10.8 Fr vs. 10.5 Fr, respectively). It is believed that the short saddle of the LAMS tightly apposes the lumen, thereby allowing secure tract maturation and appropriate vessel tamponade. These premises are questioned by this study as the GE tracts matured within 2 weeks and there was no stent-related bleeding. The Hilzo stents are not available in the US market; however, tubular stents are generally less expensive and more readily available than LAMS. While CE-LAMS can be performed “free-hand,” FCSEMS insertion requires the use of additional accessories including a 19 G needle, a 0.035-inch guidewire, a 6 Fr cystotome and occasionally a 4 mm dilation balloon (in 6/21 cases). This incurs additional costs and procedure time. However, the most challenging aspect of EUS-GE is the tendency for the jejunum to be pushed away from the stomach, which increases the risk of stent misdeployment. Jejunal displacement was observed when using a simple wire advancement through the fine-needle aspiration needle. This risk is exaggerated when additional maneuvers, such as balloon dilation and advancement of a non-cautery stent, are employed. Finally, ensuring that the proximal tip of the FCSEMS is in the small bowel before deployment is likely challenging (and, at times, impossible) using the technique described by the authors.

The use of intraluminal tubular stents, especially the fully covered variety, has historically been associated with the risk of migration. This has led to designing alternate stents with “anti-migration” mechanisms such as LAMS. Therefore, reverting to FCSEMS may seem a “step backward.” Given the novelty of

the aforementioned technique in the management of GOO, there is a lack of direct head-to-head comparisons between FCSEMS and LAMS for EUS-GE. Furthermore, the distinction between technique-related and stent-associated complications (such as misdeployment) may not always be possible. In EUS-GE, tumor ingrowth/overgrowth is not as relevant, whereas bleeding, leakage, perforation, colonic cannulation, and stent migration are significant concerns. Moreover, the stent type, length, and diameter, as well as its performance in different scenarios and the optimal intragastric portion need to be investigated further. Once these questions are answered, adding a cautery-enhanced tip to the optimal FCSEMS may render it more competitive than the LAMS.

In summary, this was a pilot study and should be interpreted with caution, given its small cohort. Drawing conclusions beyond feasibility is premature. LAMS has undeniably taken the forefront of EUS-guided GE construction, especially because of its cautery-enhanced tip. Although this publication proposes FCSEMS as a cost-saving alternative, its performance for the treatment of GOO should be evaluated with a randomized controlled trial against LAMS to prove its non-inferiority vis-à-vis different criteria (such as safety, cost-effectiveness, efficiency, technical and clinical success). In addition to accessory devices, success ultimately depends on proper patient selection and the expertise of the endoscopist. Regardless, the authors should be commended for taking a step back and thinking outside the box, while reinventing tools from within.

## Conflicts of Interest

Mouen A. Khashab is a consultant for Boston Scientific, Olympus, Medtronic, and Apollo. The other author has no potential conflicts of interest.

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