Newly Designed Laser-Cut Metal Stent with an Anchoring Hook and Thin Delivery System for Endoscopic Ultrasound–Guided Hepaticogastrostomy: Is It a Dream Stent?

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Abstract

Endoscopic ultrasound–guided hepaticogastrostomy (EUS-HGS) involves creation of an anastomosis between two intra-abdominal mobile organs, namely, liver and the stomach, with no intervening stricture. Therefore, the risk of stent migration in EUS-HGS is very high and the stent migration can lead on to severe life-threatening complications like biliary peritonitis. During last few years, there have been increased efforts to design a safe and effective stent for EUS-HGS that obviates the risk of stent migration and can also be inserted quickly, preferably, in a single-step procedure. In this news and views, we discuss an experimental study from Japan that has evaluated a new partially covered self-expandable laser cut metal stent with a thin delivery system (7.2 F) and antimigration anchoring hooks for single-step EUS-HGS in phantom and animal models.

Keywords
- endoscopic ultrasound
- bile duct
- stent

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) and transpapillary biliary drainage have been the work horse for relief of cholestasis due to biliary obstruction. However, in 3 to 12% of patients with biliary obstruction, selective canulation of common bile duct fails and these patients require either a percutaneous or a surgical drainage of the obstructed biliary system.[1] Advent of interventional endoscopic ultrasound (EUS) has opened up a plethora of endoscopic options for internal drainage of the obstructed biliary system. Various EUS-guided biliary drainage options include EUS-guided choledochoduodenostomy (EUS-CDS), EUS-guided hepaticogastrostomy (EUS-HGS), and EUS-guided antegrade stent placement (EUS-AGS). EUS-CDS seems to be the easiest of these procedures but is technically not feasible if the echo-endoscope cannot reach duodenum, either because of surgically altered anatomy or tumor invasion. EUS-AGS is relatively safer procedure, as it does not involve creation of a transmural tract but is technically feasible only if the guide wire can be negotiated across the biliary obstruction. In the above-mentioned situations EUS-HGS is the only available EUS-guided drainage option feasible. EUS-HGS involves creation of an anastomosis between two intra-abdominal mobile organs, namely, liver and the stomach. Therefore, the risk of stent migration in EUS-HGS is very high and the stent migration can lead on to severe life-threatening complications like biliary peritonitis. During last few years, there have been increased efforts to design a safe and effective stent for EUS-HGS that obviates the risk of stent migration

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and can also be inserted quickly, preferably, in a single-step procedure. In this news and views, we discuss an experimental study from Japan that has evaluated a new partially covered self-expandable laser-cut metal stent with a thin delivery system (7.2F) and antimigration anchoring hooks for EUS-HGS in phantoms and animal models.[2]

The authors designed a new partially covered laser-cut stent that is 8-mm wide and 100-mm long with main part of stent being covered with a polyurethane membrane and distal 10 mm being uncovered to prevent blockage of intrahepatic biliary radicals (Zeon Medical, Tokyo, Japan). The proximal end of the stent was equipped with three antimigration hooks and each hook was made of nickel titanium being arranged around the entire circumference of a circle with a radius of 3 mm and the outer diameter (including the hook) of 20 mm . The diameter of delivery system of this new hooked stent was 7.2F, with the tip being soft and tapered with diameter of the tip being 0.94 mm only. This soft thin tip enabled the stent to be inserted directly without dilatation of the tract and use of electrocautery. The authors compared these new hooked stents with conventional stents in phantom model, as well as animal model, for the maximum resistance force to migration, as well as feasibility and safety of EUS-HGS in pigs.

The resistance to migration was measured by inserting the stent into a round hole in the silicone wall of phantom model and the distal, uncovered end being connected to a force gauge device (Model DPX-5TR; Imada, Tokyo, Japan). The stent was retracted at a speed of 1 mm/s with a retraction robot and the maximum resistance force of each stent was measured five times and expressed as the median value. Similarly, resistance to migration both at the gastric and hepatic sides, was measured in an ex vivo model created by removing a block of the liver, stomach, duodenum, and biliary tract connected with each other from the Camborough hybrid pigs weighing 35 to 45 kg. The resistance to migration of these new hooked stents were compared with conventional braided partially covered biliary metal stents (10-mm uncovered at the distal end, 8-mm wide, and 100-mm long; Niti-S: TaeWoong Medical, Seoul, Korea).

Thereafter, EUS-HGS was performed using these new stents in animal model created by surgical ligature of bile duct in the Camborough hybrid pigs weighing 35 to 45 kg. The EUS-HGS was performed on the fifth day after surgical ligation of bile duct. EUS-HGS was performed in standard manner and either the newly designed hook stent with a thin delivery system or a conventional-braided partially covered biliary metal stent was inserted via the needle tract without use of dilatation devices or cautery. If the delivery system could not be inserted due to resistance, the transmural tract was dilated with noncautery dilatation balloon, REN (Kaneka Medix, Osaka, Japan), and thereafter the stent was inserted.

The outcome parameters assessed included the technical success rate, the procedural success rate without use of fistulous tract dilation device, adverse events, and histopathological findings. To assess the pathological findings, the pigs were sacrificed immediately or 30 days after the stent placement. The peritoneal cavity was examined to evaluate any injury to adjacent organs, and the stomach was examined to evaluate injury caused by the hooks.

The authors found that the resistance forces against migration on the distal (3.59 vs. 1.73 and 6.21 vs. 1.74 N), as well as proximal (3.58 vs. 1.5 and 5.97 vs. 1.67 N), side in both phantom and ex vivo models were significantly higher for hook stents than for conventional stents. EUS-HGS could be successfully performed with both the hooked, as well as conventional, stents in all the pigs with none of the pigs experiencing procedure-related adverse events. However, the procedural success rate without use of fistulous tract dilation device was significantly higher with hook stents (100% [10/10]) than with conventional stents (13% [1/8]; $p = 0.0002$). None of the pigs had significant organ injury on autopsy. Only one pig with implanted hooked stent had mild mucosal erosions in the stomach. There was no significant difference in the histopathological findings between pigs in whom REN was used versus not used. The authors concluded that these newly designed hooked stents may prevent stent migration as they show strong resistance to migration. Also, the insertion may be quicker and safer, as no dilatation is required for insertion of these stents.

Discussion

Interventional EUS has revolutionized the management of various gastrointestinal disorders.[3] EUS-HGS involves creation of anastomosis between stomach and the intrahepatic biliary radicles. Both the intraperitoneal organs move with respiration and therefore there is increased risk of stent migration leading on to complications that sometimes may be fatal. Also, in HGS, the stent does not traverse the stricture and therefore additional antimigration features are required. Therefore, the stents used for HGS need to possess strong antimigration properties along with other characteristics, like the intrahepatic part being uncovered to prevent blockade of intrahepatic biliary radicles and the part of stent covering the transmural tract being covered to prevent bile leak. Initially fully covered self-expanding metal stents (FCSEMS) were used for EUS-HGS.[4] However, FCSEMS had few disadvantages including stent shortening, increasing the risk of migration, as well as possibility of obstruction of side branches, of the biliary system. To decrease the risk of stent migration, various endoscopic interventions, like placement of anchoring pigtail plastic stent through the FCSEMS and use of longer stent with sufficient length in the stomach, have been used with increased safety profile.[5,6]

To offset the problem of occlusion of biliary side branches, hybrid stents were introduced for EUS-HGS. These hybrid stents are fully covered at the distal intragastric portion to prevent the bile leakage and uncovered at the proximal intrahepatic portion to prevent biliary side ducts obstruction. Also, these hybrid stents have antimigratory mechanisms flaps or flares at the gastric end with relatively long length to decrease the risk of migration.[6] The various hybrid stents available are GIOBOR (Taewoong Medical Co., Ltd., Ilsan, Korea), Hanarostent BPD (MI Tech, Seoul, Korea), and Hybrid Stent (Standard Sci Tech Inc., Seoul, South Korea). These new

stents have overcome many of the shortcoming of previous FCSEMS used for EUS-HGS but are not ideal stents. These stents require multiple steps for insertion and stent migration is still a concern. The dilatation of the transmural tract before stent insertion is a key step for stent insertion and is responsible for various adverse effects like bleeding and bile leak. A stent that enables a single-step safe EUS-HGS without tract dilatation is a dream that interventional endosonologists have been cherishing for a long time.

A single-step EUS-HGS by a new stent (DEUS, Standard Sci Tech, Seoul, South Korea) was described by Park et al.[7] This dedicated EUS stent had a 3-F tipped catheter with a 4-F tapered metal tip for the simple puncture without need of tract dilatation. Also, 7-F outer sheath delivery catheter further enhanced the pushability of the stent. This stent had 15-mm uncovered funnel-shaped portion at the hepatic end to prevent side branch occlusion and anchoring flaps at the gastric end to reduce stent migration. This new stent was shown to significantly reduce the procedure time and was found to be have comparable adverse events as FCSEMS. However, 12% patients required additional transmural tract dilatation for stent insertion, thereby offsetting the advantage of single-step insertion. Also, out of two patients in whom fistula dilatation was done prior to DEUS stent insertion, one patient developed self-limited pneumoperitoneum. This observation lends support to the fact that single-step stent placement without additional fistula dilation could markedly reduce the complications by immediately sealing the transmural track along with shortening the procedural time.

Conclusion

This new stent described in the study discussed in the current news and views have demonstrated encouraging results and single-step insertion could be successfully performed in all the animal models without the need of additional dilatation of the needle track. The performance of this exciting stent in human trials is eagerly awaited and the results from these clinical studies will only confirm whether this new stent is a panacea or not!

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Conflict of Interest
None declared.

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