

Covered self-expandable metal stents for distal biliary obstruction from pancreatic carcinoma: what type of stent is preferred?

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See “Laser-cut-type versus braided-type covered self-expandable metallic stents for distal biliary obstruction caused by pancreatic carcinoma: a retrospective comparative cohort study” by Koh Kitagawa, Akira Mitoro, Takahiro Ozutsumi, et al., on page 434–442.

Endoscopic transpapillary stenting is recommended as the first-line approach to biliary drainage for malignant distal biliary obstruction (MDBO). The stents used for endoscopic biliary drainage include plastic stents (PS) and self-expandable metal stents (SEMS). SEMS are superior to PS in terms of occlusion rate and patency and are preferred for unresectable MDBO, owing to their cost-effectiveness.¹ There are two types of SEMS: uncovered SEMS (UMS) and covered SEMS (CMS). Previous randomized controlled trials (RCTs) from Japan have shown that CMS have a longer patency period than UMS due to their ability to prevent ingrowth.^{2,3} In contrast, RCTs from overseas did not show a difference in stent patency for both types of SEMS, but stent migration was significantly more frequent in CMS.^{4,5} Therefore, the relative superiority of CMS versus UMS remains inconclusive.

The migration of CMS is an unresolved issue. Various CMS

have been developed with different stent mesh structures and anti-migration systems. However, few studies have compared the differences between these CMS designs.

In the current issue of *Clinical Endoscopy*, Kitagawa et al.⁶ reported the results of a retrospective study that compared the efficacy and safety of laser-cut and braided CMS with anti-migration systems for MDBO. This study showed that the adverse event rate and median overall survival were not significantly different between the CMS groups. However, the time to recurrent biliary obstruction (TRBO) was significantly longer in the braided CMS group than in the laser-cut CMS group ($p=0.0008$). The leading cause of stent dysfunction in both groups was stent migration, which occurred in 37.5% (9/24) of patients in the laser-cut CMS group and 13.0% (3/23) of patients in the braided CMS group. The authors hypothesized that the difference in stent migration rates may have been related to TRBO. The migration rate in the braided CMS group was comparable to that of Kogure et al.⁷ (8%) who used the same braided CMS. However, the migration rate in the laser-cut CMS group was considerably higher than that of Isayama et al.⁸ (13%) who used the same laser-cut CMS. It is difficult to account for this difference based on heterogeneity between the two studies of the laser-cut CMS.^{6,8} Although it is unknown whether Isayama et al.⁸ used chemotherapy after deploying the CMS, the use of chemotherapy by Kitagawa et al.⁶ may help account for the difference in stent migration rates. It is also possible that the

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reliability of the results reported by Kitagawa et al.⁶ were limited by the small sample size of the study. Therefore, validation of their results by studies with larger sample sizes is appropriate.

The primary goal of using SEMS is to avoid recurrent biliary obstruction and establish long-term patency. It is important to select a stent that has sufficient expansion force and low migration risk and can be appropriately placed to adapt to the individual bile duct. The WallFlex CMS used in the Kitagawa et al.⁶ study are braided cross-wired stents with a high radial force (RF), which provides a strong expansion force. It also has a strong axial force (AF) that tends to straighten the stent, causing bile duct obstruction due to kinking of the bile duct, cholecystitis, and acute pancreatitis. Therefore, we recommend that a longer stent be deployed such that the proximal end is located near the hilar region. Moreover, since these CMS have a shortening rate between 30% and 40%, it is necessary to anticipate this in stent deployment. However, these CMS can be easily removed and replaced with new SEMS in the event of stent occlusion. In contrast, laser-cut Zeostent CMS have a lower RF than the braided CMS, and since the AF is also lower, the stent is unaffected by bile duct flexion, and there is no risk of bile duct obstruction due to kinking. Moreover, stent placement is relatively easy because the stent is rarely shortened during the procedure. However, stent removal is not as straightforward compared with the braided CMS, and re-intervention methods should be carefully considered in the event of stent occlusion. Recently, knitted CMS (with hook and cross-wired structures) have been developed as a form of braided CMS. Knitted CMS have low AF and shortening rates while maintaining a strong RF due to the hook and cross-wired weave ratio. In a study of knitted CMS deployed for MDBO, Yamao et al.⁹ reported a longer median TRBO of 536 days and low stent migration rate of 5%. Therefore, it is important to understand the different characteristics of various CMS and tailor them appropriately to different patients.

The results of the Kitagawa et al.⁶ study demonstrate that stent migration remains a significant challenge associated with CMS. A lower migration rate results in a longer stent patency duration. In a multicenter retrospective analysis of risk factors for migration of CMS in MDBO, Nakai et al.¹⁰ reported that the use of chemotherapy (subdistribution hazard ratio [SHR] 4.46, $p=0.01$), use of CMS with RF ≤ 4.00 N (SHR 2.23, $p=0.03$), and presence of duodenal invasion (SHR 2.25, $p=0.02$) were significant risk factors for early stent migration. The reason for increased stent migration in patients with duodenal invasion is

unclear. However, the associations between increased stent migration rates and chemotherapy and low RF are unsurprising. The prognosis of pancreatic cancer has been improved by the development of newer and more effective chemotherapeutic agents, but stent migration rates may increase due to the resolution of biliary stricture as a result of tumor shrinkage. Therefore, the development of antimigration systems for CMS is important in extending the TRBO. Antimigration systems include partially covered, anchoring, flare-end, and dumbbell designs, although it remains unclear which design is superior. CMS with high RF, low AF, and reliable antimigration systems are ideal for achieving a longer TRBO and reducing stent-related complications in MDBO.

Conflicts of Interest

The authors have no potential conflicts of interest.

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Author Contributions

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