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Can we insert a covered stent, partially or not, in case of hilar biliary stenosis?

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DOI https://doi.org/10.1055/s-0043-120665 |
Endoscopy International Open 2017; 05: E1218–E1219

ISSN 2364-3722

In this issue of Endoscopy International Open, Kitamura et al. [1] report on their experience with a new partially-covered self-expanding metal stent (PCSEMS) in the palliative drainage of complex (Bismuth-Corlette type II to IV) malignant hilar strictures (MHS). The authors used 6-mm diameter braided-type SEMS with a silicone covering on the inner and outer surfaces, and an uncovered proximal 10-mm section with the intent to avoid biliary side branch occlusion.

SEMS were inserted bilaterally side-by side in 17 patients and results were evaluated retrospectively. All the patients received 2 SEMS, therefore 7/17 (41 %) with Bismuth – Corlette type III or IV MHS had bilateral stents but incomplete biliary drainage. Side-by-side transpapillary SEMS insertion was successful in all the cases. Stent migration occurred in 3 cases (2 distal, 1 proximal), and retreatment of recurrent biliary obstruction was always feasible with SEMS removal (n = 6), re-stenting and stent cleaning. These results support the fact that "side-by-side" insertion of multiple SEMS is highly successful and makes retreatment easier when compared to the "stent-in-stent" SEMS configuration [2]. We also believe that "side-by-side" configuration should be preferred in case of multiple SEMS placement: special care should be used to release the distal ends of the SEMS at the same level (especially if intrabiliary) in order to facilitate their cannulation in case of stent dysfunction.

The median time to recurrent biliary obstruction reported by Kitamura et al. was 79 days, shorter than in other published data [2]. The shorter time to recurrent biliary obstruction compared to other experiences could be due to the smaller (6 mm) SEMS diameter used, but also to sludge formation favored by the internal SEMS covering: actually, the majority of SEMS dysfunctions (9 out of 12) was related to the presence of biliary sludge, which is less frequently described when using uncovered SEMS. If this is true, the advantages of using PC SEMS with the intent of avoiding stent dysfunction due to tissue ingrowth will be counterbalanced by the higher risk of sludge formation. This question could obviously be clarified by a randomized study, which, however, would be very difficult to perform because of several reasons: the limited number of patients, the inhomogeneous characteristics of biliary obstruction in the setting of MHS, the potential influence of associated radio-chemotherapy, and the dissimilar level of skill and experience available in different clinical settings. The optimal diameter of multiple SEMS in MHS is also not defined. Multiple SEMS expansion in tight strictures like those involving the hepatic hilum is sometimes incomplete, so that larger SEMS (8 – 10 mm in diameter) could probably provide an improved drainage.

Kitamura et al. remark that in their series "many causes of death were the progression of cancer and exacerbation of biliary infection." Early or delayed septic complications developing in the obstructed biliary ducts are a major issue when dealing with palliative treatment of complex MHS. Septic complications, if not immediately tackled, may be fatal, contributing to the mortality rate as much as the natural progression of the neoplastic disease. Drainage of at least 30 % of the hepatic parenchyma is usually enough to relieve jaundice and to alleviate the pruritus, even if biochemical cholestasis persists due to obstruction of the remainder biliary tree. Therefore, theoretically, even in Bismuth-Corlette type III strictures, only 1 stent placed in one of the right sectorial ducts (each one drains approximately 30 % of the hepatic parenchyma) or in the left hepatic

duct (40 %) should be enough to palliate symptoms if the drained parenchyma is not atrophic [3, 4]. However, currently, drainage of at least 50 % of the parenchyma is recommended because it has been shown to be more effective [3, 5 – 7]. Nevertheless, persistent obstruction of the remaining hepatic parenchyma may lead to early or late infectious complications due to bacterial contamination of the bile, which will require further management. The actual incidence of delayed septic complications occurring at distance from the index therapeutic procedure is difficult to assess. However, it can be argued that some patients will develop potentially fatal septic complications while at home, often far away from the tertiary referral center where they have been originally treated. Acute suppurative cholangitis is an emergency, which needs active intervention and drainage (antibiotics alone are generally ineffective), and if not promptly addressed, may quickly lead to renal failure and shock. Hence, it is probable that some patients will eventually die because of septic complications and not because of neoplastic progression. Only "complete" drainage of the biliary tree would thus protect from septic complications, at least theoretically. Here is the point: while "monolateral" stenting in Type ≥ II MHS means always "incomplete" drainage, "bilateral" stenting with 2 prostheses provides "complete" drainage in Type II, but "incomplete" drainage in Types III and IV. It is therefore improper to compare "monolateral" to "bilateral" stenting in Type III and IV MHS because they will provide an incomplete drainage in both circumstances.

Two recent meta-analyses [8, 9] compared unilateral and bilateral drainage of MHS obtaining similar results in terms of jaundice palliation, complications and 30-day mortality. Some authors suggest preferring unilateral drainage due to the higher technical success [9, 10]. Many studies, included in the meta-analyses, enrolled also patients with Bismuth-Corlette type I MHS, where one stent can drain all the liver, while other used 2 stents to drain Bismuth-Corlette type III or IV MHS obtaining an incomplete drainage leaving opacified and undrained biliary ducts. The concept of unilateral and bilateral biliary drainage should then be revised according to the anatomy of the hilar stricture, and be replaced by the terms *"complete"* (all liver segments drained) and *"incomplete"* biliary drainage.

The role of covered SEMS to drain MHS is unknown. Few data are available with the *fully covered* design [11]: the risk of cholangitis due to side-branch occlusion is the major concern to their use.

A PC SEMS design, as suggested by the experience of Kitamura et al., could be an alternative, especially for the left hepatic duct, where the risk of occluding secondary branches is lower because the secondary biliary confluence (segment 4) usually occurs at distance from the main hepatic confluence.

Conclusion

In conclusion, endoscopic palliative treatment of complex MHS remains a challenging technical problem also in the era of SEMS, and should be tailored according to each specific anatomical condition. Currently available clinical experience suggests the use of multiple "side-by-side" uncovered SEMS in this setting. Future RCTs comparing "complete" to "incomplete" biliary drainage and uncovered to partially covered SEMS are desirable, yet undoubtedly difficult to perform.

Competing interests

Guido Costamagna: Cook Endoscopy, Boston Scientific, Taewoong, Given Imaging. Andrea Tringali: nothing to disclose.

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