Self-Expanding Metallic Biliary Stents: Time to Suit Up?

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Endoscopic insertion of self-expandable metal stents (SEMSs) has become the “gold standard” for palliative therapy of distal malignant biliary obstruction (MBO). Although SEMSs are superior to plastic stents due to their longer patency [1, 2], debate exists as to which type of SEMSs is best. Fully covered SEMSs (FCSEMSs) are easily removable, but are associated with increased rates of stent migration, whereas uncovered stents are not easily removable and are associated with higher occlusion rates. Multiple trials have compared FCSEMSs with uncovered SEMSs with conflicting results [3, 4].

In recent years, partially covered SEMSs (PCSEMSs) have been developed in order to minimize adverse events associated with prior SEMSs designs and to improve outcomes. Results have been inconsistent, potentially related to differences in the mechanical axial and radial forces generated by the device as well as variations in the anti-migration properties among different designs [5]. In 2012, the authors of the current study compared the partially covered Wallstent™,¹ which has a high axial force, to the partially covered WallFlex™¹ stent, which has a lower axial force [5], reporting that WallFlex™ stents had significantly less migration and longer time to recurrent biliary obstruction (RBO). The characteristics of these stents are summarized in Table 1. In recent years, fully covered WallFlex™ stents (Boston Scientific Corp), incorporating many of the design features of their partially covered stent, have become commercially available.

In the current issue of *Digestive Diseases and Sciences*, Kogure et al. [6] report the results of a multicenter, prospective study (WATCH-2), conducted in 16 referral centers in Japan, where 151 cases with unresectable distal MBO managed with fully covered WallFlex™ stents were compared with a historical cohort of 141 cases, in their previously

reported WATCH study who underwent the insertion of partially covered WallFlex™ stents. There were no significant differences in the rate of RBO (29 vs. 33%; $P=0.451$), time to RBO (318 vs. 373 days; $P=0.382$), or survival (229 vs. 196 days; $P=0.177$) between the two groups. The rate of stent migration also did not differ significantly (14 vs. 8%; $P=0.113$). The results are similar to a recent retrospective analysis by Yokota et al. [7] comparing the clinical outcome of uncovered, partially covered, and fully covered of WallFlex™ stents in patients with MBO. Although there was no significant difference in patient survival among the three groups, the rate of RBO was numerically, but not statistically significantly lower with partially covered SEMSs (28.6%) as compared to uncovered (45.4%; $P=0.215$) and fully covered (55.2%; $P=0.106$) stents.

A potential, but debatable, complication of FCSEMSs is cholecystitis due to the occlusion of the cystic duct orifice. In this study, 6 patients (4%) with FCSEMSs developed cholecystitis after a median of 4 days versus 14 patients (10%) with PCSEMSs after a median of 20 days ($P=0.061$) in the prior study. Thus, this study does not support the hypothesis that FCSEMSs are associated with an increased risk of cholecystitis. Many, if not most, patients undergoing palliative stenting for MBO also receive radiation and/or chemotherapy. The latter treatments have been associated with early stent migration and RBO [8, 9]. In the current study, however, the authors reported no significant difference in the rate of stent migration among patients with or without chemoradiation (13 vs. 18%; $P=0.475$).

A promising technique to further improve stent patency and patient survival is intraductal radiofrequency ablation (RFA) applied to the obstructing tumor prior to stent insertion in order to delay tumor ingrowth, a common cause of stent occlusion. A recent systematic review and meta-analysis by Sofi et al. [10] showed the pooled weighted mean difference in stent patency was 50.6 days (95% CI 32.83–68.48) favoring patients receiving RFA. They also showed improved survival in patients treated undergoing RFA (HR 1.395; 95% CI 1.145–1.7; $P<0.001$). Although

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Table 1 Characteristics of partially covered Wallstents and partially covered WallFlex stents

Stent type	WallFlex™	Wallstent™
Wire	Platinum-cored nitinol	Tantalum-cored Elgiloy
Cover membrane	Silicone	Silicone
Stent edge	Flared and looped	Non-flared and sharp
Radial force (N)	4.70	3.41
Axial force (N)	0.65	0.95

N Newton

RFA appears to be safe and is associated with improved stent patency in patients with malignant biliary strictures, more prospective studies are needed.

Given the recent advances in medical treatment with associated improvements in the prognosis of unresectable pancreatobiliary malignancies and longer life expectancy, endoscopic re-interventions are often required. The study by Kogure et al. is important as it demonstrates that newly developed FCSEMSs can provide effective relief for MBO while, at the same time, facilitating removal while not increasing the risk of stent migration. The debate regarding the use of FCSEMSs versus PCSEMSs is likely to continue pending the completion of studies evaluating the safety and efficacy of these stents.

Key Points

- In patients with longer life expectancy, FCSEMSs may be superior to PCSEMSs due to easy removability at the time of re-intervention.
- Fully covered WallFlex™ stents have flared ends that may reduce the rate of stent migration.
- Survival of patients with malignant biliary obstruction may be improved with RFA.
- Further studies are warranted in determining the benefits of RFA for the preservation of stent patency.

Compliance with ethical standards

Conflict of interest Dr. Kahaleh is a consultant for Boston Scientific, Xlumina, and Maunakea and does research for Gore, MI Tech, Pin-

nacle, and Maunakea. The other authors have no conflicts of interest to declare.

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