Self-Expanding Metal Stents for Pancreatic Tumors: Expanding the Possibilities, Decreasing the Costs and Risks

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Unresectable pancreatic and peri-pancreatic tumors obstructing the duodenum and bile duct carry a poor prognosis. Due to the lack of definitive therapeutic options, past treatments consisted mostly of surgical bypass for symptom palliation. Recently, endoscopically deployed biliary and duodenal self-expanding metal stents (SEMS) have supplanted surgical bypass in this setting due to their efficacy in relieving biliary and duodenal obstruction with consequent symptom relief as described in a 2007 meta-analysis [1]. Similarly, a multicenter randomized trial [2] and a recent, prospective multicenter study [3] reported the efficacy of duodenal stenting in the relief of obstructive symptoms in patients with gastroduodenal obstruction. When directly comparing endoscopic and surgical techniques, a meta-analysis from the Cochrane database in 2006 reported similar technical success and short-term efficacy in improving jaundice in patients with unresectable malignancy [4], although endoscopic interventions were associated with less morbidity and a shorter hospitalization [4]. In a prospective, randomized study comparing endoscopic versus surgical intervention for duodenal obstruction, no differences in mortality or morbidity were reported, although endoscopic therapy was associated with a faster resumption of oral intake after the intervention and a decreased length of hospital stay [5].

Simultaneous placement of biliary and duodenal SEMS has been performed infrequently due to technical difficulties, concern over stent dysfunction, and high rates of complications, specifically stent restenosis. Biliary SEMS

are difficult to place after duodenal stents, often requiring a more complex rendezvous procedure for successful placement in which the bile duct is accessed and cannulated in an antegrade fashion through the liver endoscopically using an endoscopic ultrasound-guided (EUS) approach or percutaneously by an interventional radiologist. Moreover, higher rates of biliary stent dysfunction were reported when duodenal stents were present [6]. Recently, however, several small case series have reported that simultaneous biliary and enteral SEMS placement is associated with 82–100 % technical and clinical success and a 15–58 % complication rate, mainly stent stenosis, although many of these studies included a small number of patients and had minimal post-procedure evaluation [7–11].

In this issue of *Digestive Diseases and Sciences*, Canena et al. [12] provide additional evidence that simultaneous biliary and duodenal SEMS are an acceptable therapeutic option for patients with unresectable pancreatic or peri-pancreatic malignancy. Canena et al. enrolled 50 patients, a larger sample size than reported in previous studies, providing a statistically more robust database. Technical success was achieved in 100 % of the included patients: Endoscopic placement of biliary stents was achieved in 42 out of 50 patients, with the remaining eight patients requiring a percutaneous rendezvous procedure for placement. The highest percentage of failed endoscopic biliary stent placements was when the duodenal stricture involved the ampulla; in these patients, endoscopic biliary SEMS deployment was only possible when a previously placed plastic biliary stent was present and could be exchanged for a SEMS over a guidewire.

In the discussed study, clinical success defined as (1) decreasing serum bilirubin concentrations with the resolution of symptoms of jaundice and pruritus for biliary SEMS and (2) improvement of oral intake with improvement of

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the gastric outlet obstruction score (GOOSS scale) for enteral stents was achieved in the majority of patients. All patients responded to biliary stent placement, and 50 % of patients responded to duodenal stent placement with a statistically significant improvement in the GOOSS score. An early complication rate of 4 % was reported, with two patients developing mild post-ERCP pancreatitis. A 40 % rate of stent stenosis requiring endoscopic revision was reported, with 11 out of 50 patients developing duodenal stent occlusion and 17 out of 50 patients developing biliary stent occlusion, with associated cholangitis in eight out of the 17. All the patients were managed endoscopically without requiring surgical intervention and without affecting overall mortality. Average stent patency was 34 and 27 weeks for biliary and duodenal stents, respectively, comparable to the results reported in previous smaller studies [6–11]. No procedure-related mortality was noted. The majority of patients in the study (60 %) required no additional intervention after the initial endoscopic procedure until the time of their death.

This article, in addition to prior smaller published studies [6–11], strengthens the evidence supporting endoscopic rather than surgical management of patients with advanced, unresectable pancreatic or peri-pancreatic cancer who develop biliary and duodenal obstruction [12]. Although concerns over technical success have limited application of these procedures in the past, technical and clinical success after endoscopic intervention in all studies is excellent when performed in tertiary referral centers. Complication rates from endoscopic procedures are reasonable and can be managed endoscopically without influencing overall life expectancy. Furthermore, while concerns over enteral stents increasing the failure rate of biliary stents are warranted, such complications do not seem to increase mortality even when cholangitis develops [6–11]. In addition, cost-comparison analyses between surgical and endoscopic therapy have favored endoscopic management. A randomized study from 2010 showed higher total costs per patient for gastrojejunostomy compared to endoscopic stent placement in patients with malignant gastric outlet obstruction (€12,433 vs €8,819) with a cost-effectiveness ratio of an extra €164/day [13]. Similarly, a retrospective study from 2012 comparing Medicare claims hospitalization data showed a median cost of \$15,366 for endoscopic stenting in patients with malignant gastric outlet obstruction as compared to \$27,391 for gastrojejunostomy [14].

Possible drawbacks to the use of simultaneous biliary and duodenal SEMS, as reported in this and in prior studies [6–11], include the need for a percutaneous rendezvous for biliary stent placement when enteral stenting was performed first. This can be alleviated, as noted, when a plastic biliary stent is placed prior to duodenal stent

placement, which allows for SEMS placement over a guidewire through an enteral stent. This may also be addressed by using EUS-guided biliary stent placement. EUS-guided biliary access is efficacious with an acceptable safety profile in patients with failed attempted endoscopic retrograde pancreatography (ERCP) biliary drainage [15], or as a less invasive alternative to a rendezvous procedure in patients with failed biliary SEMS placement through a duodenal stent by ERCP [16].

In summary, Canena et al. describe the largest experience to date with endoscopic relief of biliary and duodenal obstruction in patients with unresectable pancreatic and peri-pancreatic malignancy, highlighting the considerable technical progress that has occurred since the era of open surgical bypass. In a majority of patients, effective palliation can be achieved with one endoscopic procedure at lower cost when compared with the surgical alternative. In those patients who develop complications of stent restenosis, the majority can be handled effectively with endoscopic revision without affecting overall mortality, even in the setting of cholangitis. Providing palliation for these patients in a way that avoids invasive surgery and shortens post-procedure hospitalization at a lower overall cost represents a major therapeutic advance.

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