Metallic biliary stents for malignant obstructive jaundice: a review

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Affecting 8-10 patients per 100 000 population, pancreatic cancer is the primary cause of malignant obstructive jaundice and is the presenting feature in over three quarters of these patients[1]. Unfortunately, using modern imaging techniques, such as endoscopic ultrasound or pancreatic protocol computed tomography with vascular reconstruction, 80% - 90% prove unresectable for cure[2,3]. Historically, this jaundice was treated surgically with biliary bypass. Over the past 10 years, however, multiple studies have shown comparable palliation (3-6 month survival) with percutaneous or endoscopic placement of a polyethylene prostheses[4-6]. Moreover, our group, as well as others, have shown that despite comparable survivals, resource utilization (costs) to time of death for the endoscopic group are approximately one-half of those expended in surgically treated patients[7].

Despite this palliative advance in an often aged and infirm group of patients, however, stent occlusion has proven problematic. A consequence of bacterial biofilm development, attempts to prolong patency with chronic antibiotic therapy, ursodeoxycholic acid, change in the type of polymer used or coating the inner lining with a variety of agents to preclude bacterial colonization have all proven unsuccessful[8]. It was with this background that the first expandable metallic stent was introduced. This review will summarize the current state of our knowledge, new developments in self-expandable metal stent (SEMS) technology, and areas in which additional studies are needed.

WHAT DO WE KNOW ABOUT EXPANDABLE STENT TECHNOLOGY IN THE BILIARY TREE?

For one, we know that the vast majority of literature has utilized the open mesh stainless-steel Wallstents[9-16] (Microvasive Inc. Natick, MA). However, a number of additional SEMS (Table 1) have recently been introduced and variably studied. The latter included closed-weave prostheses fashioned from nitinol (Diamon stent, Microvasive Inc., Natick, MA; and Za stent, Wilson-Cook Inc., Winston-Salem, MA) or stainless steel (Spiral Z, Wilson-Cook Inc.)[17-23]. They also included the Biliary Endocoil (Intratherapeutics, Eden, Prairie, MN), a tightly coiled nitinol spiral which ostensibly precludes tumor ingrowth[24]. Not only these stents have different physical properties by virtue of wire material, guage, and configuration, but also their delivery systems and their degree of foreshortening at time of delivery differ. For instance, neither Spiral Z nor Za stents foreshorten. Diamond and Wallstents shorten by a third and Endocoils by a half.

We also know that, to date, there has been no study which has randomized metallic stent placement against surgical bypass in the palliation of malignant obstructive jaundice. There are, however, numerous randomized and controlled studies randomizing Wallstents against plastic prostheses, all showing superior patency of the former[4,10-13]. In a largest study, 182 patients with inoperable distal bile duct obstruction were randomized to plastic stent versus SEMS. At 30 days, one-quarter of the plastic prostheses were occluded compared with 5% of the Wallstents[11]. Although survival was unchanged, there was a two-fold prolongation in patency rate compared to plastic stents. Comparable, albeit longer stent survival (Wallstent 273 days, plastic 126 days) was reported by Davids et al in a well-designed European trial[10]. Additional, non-randomized studies have looked at the use of single or dual Wallstents in Klatskin-type tumor[15-17]. Dual stenting was not only associated with a decreased risk of cholangitis, but a decreased need for reintervention, and, in one study, approximately a two-fold survival[16].

Table 1  Commercially available self-expandable biliary stents for malignant obstructive jaundice

| Stent   | Wallstent | Endocoil | Diamond | Spiral Z | Za |
|---------|-----------|----------|---------|----------|----|
| Design  | Mesh      | Spiral coi | Mesh    | Spiral   | Mesh |
| Material| Stainless steel | Nitinol | Nitinol | Stainless steel | Nitinol |
| Length (cm) | 4.2/6.8/8 | 6/7.5 | 4/6/8 | 5.7/7.5 | 4/6/8 |
| Diameter (mm) | 8/10 | 6/8 | 10 | 10 | 10 |
| Steent foreshortening | Yes | Yes | Yes | No | No |
| Introducer diameter (Fr) | 7.5/8 | 8/10 | 9 | 8.5 | 8.5 |

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CAN THE ABOVE RESULTS BE GENERALIZED TO OTHER METALLIC PROSTHESSES?

Probably not. Up to now there has been no study randomizing patients to Wallstents versus other SEMS. Dumonceau et al, however, reported 23 patients with malignant obstructive jaundice treated with Diamond stents and retrospectively compared them with an age and illness matched group treated with Wallstents\cite{19}. Technical insertion, incidence of recurrent jaundice, and life table analyses of bile duct patency were comparable with both types of prostheses. In contrast, Raijman et al placed Diamond stents in 21 patients noting delivery system kinking in 2 and stent distortion or displacement in 3\cite{22}. Moreover, mean patency was only 2.1 months compared to the 9.7 months of Wallstent patency in their historical controls. Seeccoomar et al have also noted similar results\cite{23}. In one of the few comparative studies reported to date, Yoo et al placed Diamond stents in 75 patients, plastic prostheses in 58 and Spiral Z stents in 20. The success rate of insertion was comparable whereas the patency at 4 months was 63%, 24%, and 77%, respectively\cite{24}. They concluded that the patency rate of both SEMS was comparable and improved over plastic prostheses.

In addition to the above, there have been a few studies looking at biliary Endocoils but no comparative studies. In the latest series abstracted, 25 patients, including 6 with benign stenoses had Endocoil insertion and were followed for a mean of 13 months\cite{20}. Stents were successfully deployed in 23/25 (92%) and jaundice improved in 22/24 (92%). However, 50% of stents were dysfunctional at a mean of 7 months. Data are even sparser for the Spiral Zstent\cite{21} although a multi-center US trial is currently underway.

WHAT ELSE DO WE KNOW?

We recognize that in contrast to bacterial biofilm occlusion of plastic prostheses\cite{8}, SEMS dysfunction is usually a consequence of tumor ingrowth or overgrowth or elicitation of mucosal hyperplasia at the site of individual metal stenets\cite{27}. Whether all wire materials and gauges elicit comparable hyperplasia is unknown but common sense suggests that larger weave stents may allow more tumor ingrowth than tighter weaves. Wallstents may also become dysfunctional by local duct perforation at the proximal or distal ends, particularly if acutely angulated. Likewise, their exposed distal wires may cause prosthesis dysfunction by ulceration and impaction into the contralateral duodenal wall. Finally, Endocoils fail by virtue of migration or stent infolding. The latter may allow elicitation of granulation tissue or tumor ingrowth\cite{28}.

Despite our knowledge about the mechanism of dysfunction, the ideal therapy of recurrent jaundice in a patient with an imbedded SEMS remains controversial. Extraction of cholesterol and bile salt debris above a partially occluded stent is temporizing only and attempts to cauterize lumenal tissue are usually unsuccessful. Most endoscopists will usually place one or two plastic stents through a SEMS although an additional SEMS may sometimes prove useful. This is currently my sole use of the biliary Endocoil\cite{9}.

IN ADDITION TO WHAT DO WE KNOW, WHAT DO WE THINK WE KNOW?

We think that despite a 30 to 40-fold increase in cost of plastic stents as opposed to Wallstents, the latter are still cost-effective in patients with malignant obstructive jaundice\cite{10}. These data are derived from the incremental expense associated with repeat ERCP in patients who outlive their plastic stents. In an attempt to better define which patients with malignant jaundice would benefit from a SEMS, Prat et al reviewed a variety of clinical, biochemical, and imaging criteria. Patients with small tumors (<3cm) and normal albumen as well as those with good performance status were most likely to survive >6 months and were felt to benefit from a Wallstent\cite{13}. Those who survived <3 months were more likely to have larger tumors, metastases, low proteins, and poor performance status and should be considered for plastic prostheses. Unfortunately, this leaves a large number of patients in whom treatment remains uncertain. I would personally add that SEMS should be con sidered in patients who repeatedly occlude plastic prostheses or those who reside in geographically distant locations or those who do not have access to ERCP in their community.

We also think that covering a SEMS does not necessarily increase the patency rate\cite{29}. Not only is the migration rate increased if the stent is fully covered, but bacterial biofilms and mucosal hyperplasia are problematic in stents that are only partially covered. Recent studies, most using historical controls, have questioned this\cite{30-36}. For instance, Shim et al placed polyure thane-covered Z stents in 29 patients, following them for a mean of 15 months\cite{30}. Successfully inserting 32/34 (94%) prostheses, there were early complications related to sludge in 19% and tumor/tissue ingrowth or overgrowth in another 21%. Median patient survival was 15.8 months and the authors concluded that covered Z stents improved long-term palliation of malignant biliary strictures. Recent abstracts have also recently been published placing covered Wallstents and Diamond stents with variable results\cite{31-36}.

WHAT DO WE NEED TO KNOW FOR THE FUTURE?

We desperately need comparative studies between different SEMS and need true prospective studies.
randomizing covered versus uncovered SEMS. We need better algorithms using clinical data to predict survival and define who is likely to benefit from a SEMS as opposed to selecting patients who would be equally well palliated with a much cheaper plastic prosthesis. We need better knowledge about the elicitation of mucosal hyperplasia and mechanisms to prevent this. Ultimately, we will need new materials, perhaps expandable mesh plastic polymers, cotton weaves impregnated with not only hardening agents but also antibiotics or chemotherapeutic agents, or metals that use a magnetic field or thermocouple to limit local tumor growth or treat ingrowth. If the precursor 10 years are any indication of the future 10, there will be new technologies that will be introduced and marketed before their advantages or disadvantages are fully known.

Figure 1  Currently available expandable metallic prostheses top to bottom: conventional Z, Spiral Z, Diamond, covered and uncovered Wallstent, and Za stent.
Figure 2  Dual Wallstents in patient with multiple biliary strictures from metastatic colorectal carcinoma. Arrows depict Biliary Endocoil placed for mucosal hyperplasia and recurrent jaundice.
Figure 3  Diamond stent (large arrows) placed into the biliary tree, and Wallstent (small arrow) placed into the pancreatic duct in patient with islet cell cancer and recurrent pancreaticobiliary sepsis.
Figure 4  Za stent placement in patient with distal malignant biliary stricture.
Figure 5  Spiral Z stent inserted in patient with obstructive jaundice from cholangiocarcinoma.
Figure 6  Expandable biliary endoprostheses imbed in tissue and cannot be retrieved. The exception is the biliary endocoil which can theoretically be retrieved by grabbing the distal end with a foreign body retriever.
