Pancreatic and biliary stents

The ASGE Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methodology is used, performing a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review, the MEDLINE database was searched through February 2011 for articles related to sphincter of Oddi manometry and sphincter of Oddi dysfunction.

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BACKGROUND

Biliary and pancreatic stents are tubular devices made of plastic or metal used primarily to establish patency of an obstructed bile or pancreatic duct. Stents may also be used to treat biliary/pancreatic leaks or to prevent post-ERCP pancreatitis. This report is an update of the technical considerations of available stents including indications for their use, efficacy, safety, and financial considerations.

TECHNOLOGY UNDER REVIEW

Plastic stents

Biliary. Plastic biliary stents are composed of polyethylene, polyurethane, or Teflon[1] (Table 1). Stent diameter and length vary from 5F to 12F and 1 to 18 cm, respectively (Table 1). Stents that are 10F require an endoscope with a 3.7-mm accessory channel; larger stents (11.5F and larger) require a 4.2-mm channel. Plastic biliary stents are available in a variety of configurations. Pigtail stents are coiled at 1 or both ends (single or double pigtail). Side holes are placed along the curved pigtail ends. Flanged stents, which may be straight, angled, or curved, have a single flap proximally and distally with a side hole or 4 flaps proximally and distally without side holes in the Tannenbaum design.

Stent modifications have been developed to decrease biofilm formation, thereby potentially increasing patency time. These include specialized coatings (ConMed, Utica, NY), a distal windsock design (Cook Medical, Winston-Salem, NC), a double-layer design (Olympus America, Center Valley, Pa), and a winged stent without a central lumen (GI Supply, Camp Hill, Pa) (Table 1). No studies to date have consistently shown increased patency time.

All plastic stents are radiopaque. Some have additional markers proximally and distally. Stents are available individually or in combination with introducer kits.

Pancreatic. Pancreatic plastic stents are made primarily of polyethylene materials. Pancreatic stent sizes range from 2 to 25 cm in length and 3F to 11.5F in diameter (Table 2). Pancreatic stents are either straight, curved, wedge, or single pigtail. Most pancreatic stents have side holes throughout the length of the stent to facilitate drainage of the pancreatic side ducts. A winged stent (ViaDuct, GI Supply) allows pancreatic juice to drain around the stent rather than through the stent lumen. Various designs are available depending on the desired duration of stenting. Stents with an internal flange are used for prolonged stenting; stents with no internal flange are used to promote spontaneous migration for short-term stenting. Most pancreatic stents have a mechanism (eg, distal flange, pigtail) to prevent internal migration.

Because of the smaller diameter of pancreatic stents, the majority are usually deployed with only a guidewire and pushing catheter. Larger diameter stents (8.5F and larger) are available with kits and an introducer.

TABLE 1. Biliary stents

	Length, cm	Diameter, F	Shapes	Flaps	Material	Price: stent/system, US$
Boston Scientific Advanix/ Naviflex RX	5-15	7, 8.5, 10	Duodenal bend, center bend, double pigtail	Single external/internal	Polyethylene	89/219
Boston Scientific Flexima	5-15	7, 8.5, 10, 11.5	Straight	Single external/internal	Polyurethane	79/166
Boston Scientific Percuflex	5-15	7, 10	Curved	Single external/internal	Polyethylene ethyl and vinyl acetate blend	79/130
Boston Scientific C-Flex	5-15	7, 10	Double pigtail	Pigtail	Proprietary	79/130
ConMed Hydroduct	4-15	7, 10, 12	Angled, straight, curved, double pigtail	Single external/internal	Polyurethane with hydrophilic hydromer coating	72/146
Cook Cotton-Huibregtse	5-15	7, 8.5, 10, 11.5	Angled	Single external/internal	Polyethylene	69/145
Cook Cotton-Leung	5-18	7, 8.5, 10, 11.5	Curved	Single external/internal	Polyethylene	69/145

	Length, cm	Diameter (F)	Shapes	Flaps	Material	Price: stent/system, US$
Cook Cotton-Leung Sof-Flex	5-15	7, 10	Curved	Single external/internal	Polyethylene/polyurethane blend	69/145
Cook ST-2 Tannenbaum	5-15	8.5, 10, 11.5	Curved	4 external/internal	Teflon	69/145
Cook Fusion Marathon Antireflux	5-12	10	Curved	4 external/internal with external valve	Polyethylene with Teflon sleeve	69/145
Cook Solus	1-15	10	Double pigtail	Pigtail	Polyethylene/polyurethane blend	69/145
Cook Zimmon	2-18	5, 6, 7, 8, 10	Double pigtail	Pigtail	Polyethylene	69/145
Hobbs Medical (Stafford Springs, Conn)	4-15	7, 10	Curved, Double pigtail	Single external/internal, pigtail	Soft polymer blend	44/90

	Length, cm	Diameter, F	Shapes	Flaps	Material	Price: stent/system, US$
Olympus Quick Place V Double Layer	3-15	10	Duodenal bend, center bend	4 external/internal	Inner layer: Perfluoro, middle layer: stainless steel, outer layer: polyamide elastomer	274/365
Olympus Quick Place V	3-15	7, 8.5, 10	Straight, duodenal bend, double pigtail	Single external/internal, pigtail	Polyethylene	78/169
GI Supply ViaDuct	5-15	7, 10	Winged straight	Single external/internal	Polyurethane	68/103

	Length, cm	Diameter, F	Shapes	Flaps	Material	Price: stent/system or stent + pusher
Cook Geenan	2-15	3, 4, 5, 6, 7, 8.5, 10, 11.5	Curved	2 external/internal or 2 external	Polyethylene	69/145
Cook Geenan Sof-Flex	3-12	5	Curved	2 internal/external or 2 external	Polyethylene and polyurethane blend	69/145
Cook Johlin Wedge	8-22	8.5, 10	Wedge	None	Polyethylene and polyurethane blend	69/145
Cook Zimmon	2-25	3, 4, 5, 6, 7, 8.5, 10	Single pigtail	External pigtail with/without single internal flap	Polyethylene	69/145
GI Supply ViaDuct	3-12	5, 7	Winged	Single external pigtail, single external, single external/internal	Polyurethane	58/93
Hobbs Medical Freeman Flexi	2-18	3, 4, 5, 7	Straight or single pigtail	Single pigtail with/without internal flap; 2 external, single internal	Soft polymer	44-48/50-54

SELF-EXPANDABLE METAL STENTS

Self-expanding metal stents (SEMSs) were developed to increase stent diameter, thereby increasing the patency duration and reducing recurrent obstruction.[2] SEMSs are constructed of a variety of metal alloys (eg, nitinol [Elgiloy, Specialty Metals, Elgin, Ill). These materials are used to achieve adequate radial expansile force without sacrificing flexibility and conformability to the duct.[3] SEMSs range from 4 to 12 cm in length with diameters when expanded ranging from 6 to 10 mm (Table 3).

TABLE 2. Pancreatic stents

	Boston Scientific Wallstent RX	Boston Scientific WallFlex	ConMed Flexxus	Gore Viabil	Cook Zilver, Zilver 635, Fusion Zilver	Olympus X-Suit Nir
Length, cm	4, 6, 8, 10	4, 6, 8, 10	4, 6, 8, 10	4, 6, 8, 10	4, 6, 8	4, 6, 8, 10
Diameter, mm	8, 10	8, 10	8, 10	8, 10	6, 8, 10	8.10
Delivery system, F	8	8, 8.5	7.5	8.5	6 (Zilver 635), 7	7.5
Material	Elgiloy	Platinol	Nitinol	Nitinol	Nitinol	Nitinol
Covering	Uncovered, partially covered (silicone polymer)	Uncovered, partially covered, fully covered (silicone polymer)	Uncovered	Fully covered (PTFE/FEP) with/without drainage holes	Uncovered	Uncovered
Shortening	Yes	Yes	Yes	No	No	Yes
Reconstrain	Yes	Yes	No	No	No	No
Design	Braided closed cell	Braided closed cell, retrieval loop	Laser cut open cell	Wound with open cell	Laser cut open cell	Water-jet cut closed cell
Price, US$	Uncovered, 1595; uncovered Rx, 1695; partially covered, 1954; partially covered Rx, 1995	Uncovered, 2039; partially covered, 2750; fully covered, 2850	1607-1821	2600	1503-1563	1606

PTFE/FEP, Polytetrafluoroethylene/fluorinated ethylene. propylene.

TABLE 3. Self-expandable metal stents

	EndoChoice Bonastent (Atlanta, Ga)	Taewoong Medical Niti–S (D type) (Seoul, Korea)	Taewoong Medical Niti–S (S type)	Taewoong Medical COMVI	Taewoong Medical T&Y	Merit Medical (South Jordan, Utah) Alimaxx-B
Length, cm	5, 6, 7, 8, 9, 10	4, 5, 6, 7, 8, 9, 10, 12	4, 5, 6, 7, 8, 9, 10, 12	4, 5, 6, 7, 8, 9, 10	4, 5, 6, 7, 8, 9, 10,12	4, 6, 9
Diameter, mm	8, 10	8, 10	8, 10	8, 10	10	8, 10
Delivery system, F	7-8	8.5	8.5	9	8 (T), 8.5 (Y)	6.5
Material	Nitinol	Nitinol	Nitinol	Nitinol	Nitinol	Nitinol
Covering	Uncovered, fully covered (silicone)	Uncovered	Uncovered, fully covered (silicone)	Fully covered (PTFE)	Uncovered	Uncovered
Shortening	Yes	Yes	Yes	Yes	Yes	Yes
Reconstrain	No	No	No	No	No	No
Design	Hook and cross open cell, retrieval loop	Hand woven, open cell	Hand woven, open cell, retrieval loop	Hand woven, open cell	Hand woven, open cell, central large open mesh	Laser cut, open cell
Price, US$	1795	1100	1100	1100	1100	1200

PTFE, Polytetrafluoroethylene.

Most SEMSs are constrained by an outer sheath with a diameter of 8.5F or smaller, allowing use with a therapeutic or diagnostic duodenoscope. After placement in the duct, the outer sheath is withdrawn, allowing the stent to expand. A slight variation is the Viabil stent (Gore Medical, Flagstaff, Ariz), which is constrained by a thin filament tightly wound around the stent. The filament is pulled to allow stent expansion. Some stents will allow recapturing and repositioning during deployment. Shortening may occur with certain SEMSs after placement (Table 3).

All SEMS are radiopaque. Most models have additional proximal and distal markers made of a different metal such as gold and titanium. Flared ends or antimigration fins are designed to prevent migration.

SEMSs are covered, partially covered, or uncovered. Coverings include material made of polytetrafluoroethyl-

ene, polytetrafluoroethylene/fluorinated ethylene propylene, or silicone membranes. The covering is on the exterior (Wallstent or Wallflex, Boston Scientific, Natick, Mass; Bonastent, EndoChoice, Alpharetta, Ga; COMVI and Niti-S, Taewoong Medical, Seoul, Korea) or interior (Viabil) of the stent. Because of tumor ingrowth or benign tissue hyperplasia, uncovered stents are difficult to extract after being inserted.[4,5] Partially or totally covered SEMSs can be repositioned or fully removed with the use of a snare or rat-tooth forceps. Some stents have a retrieval loop, such as the Wallflex, that can facilitate its removal and repositioning after initial placement.

Efficacy and outcomes

Biliary. *Malignant obstruction.* Placement of stents in patients with malignant biliary obstruction improves jaundice, pruritus, anorexia, and overall quality of life.[6,7] Both plastic stents and SEMSs relieve the obstruction caused by malignant disease. Plastic stent patency time is increased with stents of a 10F caliber and larger.[8,9] However, stents with diameter of 11.5F or 12F have not been shown to increase patency compared with 10F stents.[10,11] Occlusion of larger diameter stents (10F or larger) usually occurs at 3 to 6 months.[12-15] SEMSs have longer patency compared with plastic stents.[16-20] Plastic stents may be more cost-effective in patients with distant metastases and a short life expectancy.[21]

Traditionally, SEMSs have been reserved for patients with inoperable biliary or pancreatic cancer. More recently, covered and short uncovered SEMSs have been used effectively as a bridge to surgery in resectable patients or in patients who are borderline resectable undergoing neoadjuvant therapy.[22-24]

Both plastic and metal stents (SEMSs) are used for hilar tumors, but few data are available to guide the choice of stent. One short-term study showed metal stents to have superior patency compared with plastic stents for inoperable hilar cancer.[25] For bilateral drainage, SEMSs with large open cell interstices to place a stent within a stent in a Y configuration or smaller 6F diameter delivery catheters (placed side-by-side simultaneously) have resulted in high technical and clinical success rates.[26-28]

Benign biliary strictures. The majority of benign biliary strictures are caused by postsurgical injuries (eg, cholecystectomy, liver transplantation) or chronic inflammatory disorders (eg, chronic pancreatitis, primary sclerosing cholangitis). The technical success rates for stenting benign strictures are greater than 90%.[29-35] Clinical success rates for stricture resolution range from 70% to 95% for postoperative strictures; superior stricture resolution rates are achieved by placement of multiple plastic stents side by side.[29-25] A review of 47 studies of benign extrahepatic bile duct strictures showed a clinical success rate of 94% with multiple stents versus 59% with single plastic stents.[36]

Biliary strictures related to chronic pancreatitis are more resistant to treatment with endoscopic stenting, with greater long-term failure in resolving the stricture.[37-39] Using multiple plastic stents, long-term stricture resolution in chronic pancreatitis may reach 44% to 60%.[40,41] Stent dysfunction and adverse events occur in as many as 40% of patients treated with sequential stenting for chronic pancreatitis.[37]

Because of the difficulty in removing uncovered SEMSs, their use in benign biliary strictures is limited.[36] Small recent series have demonstrated the successful use of covered SEMSs in the treatment of benign biliary strictures. One study showed resolution of benign biliary strictures from a variety of causes in 77% of patients after having a covered SEMS placed and later removed.[42] Chronic pancreatitis strictures still have worse outcomes compared with other types of benign biliary strictures, with long-term stricture resolution in 58% to 72% of patients.[42,43] Treatment of post-liver transplantation anastamotic stricture showed stricture resolution in 81% to 95% of cases with covered SEMSs.[44,45] In all studies, the covered SEMSs could be removed in the majority (>95%) of patients.

Biliary leaks. Postoperative bile leaks can be successfully treated with placement of a single plastic stent with or without sphincterotomy in 70% to 100% of patients.[46-50] Small case series describe the successful use of partially or fully covered SEMSs to seal large complex leaks and leaks where previous endoscopic therapy with plastic stents failed.[51-53]

Bile duct stones. Biliary stents can be placed to relieve biliary obstruction in patients with multiple large bile duct stones that cannot be completely cleared from the bile duct. Temporary plastic stent placement can reduce the number and size of stones, facilitating complete stone clearance in more than 90% of cases on subsequent ERCP.[54-56] A small case series showed a similar success rate with temporary placement of a covered SEMS.[57]

Pancreas. *Pancreatic strictures.* Pancreatic duct stenting can resolve or improve symptoms in chronic pancreatitis patients with pancreatic duct strictures. With pain relief as the endpoint, placement of plastic stents across pancreatic strictures has 70% to 94% short-term and 52% to 80% long-term effectiveness.[58-63] Stenting is usually required for multiple months with frequent stent changes.

Fully-covered SEMSs have been used to treat chronic pancreatitis strictures in small uncontrolled studies.[64,65] After placement for 2 to 3 months, the SEMSs were removed with resolution of strictures in all patients and with some improvement in pain. Frequent adverse events of stent migration and stent-induced strictures were reported.

In very small case series, plastic or metal stents were placed in the pancreatic duct across a malignant stricture to relieve pain thought to be caused by ductal obstruction. Pain was decreased in 75% to 90% of patients.[66,67]

Pancreatic leaks/fistulae. Plastic stents, particularly when bridging the entire leak is possible, are effective in treating pancreatic duct leak in 77% to 94% of cases.[68-70] Effectiveness is reduced in complete duct disruption.

Pancreas divisum. Three small series describe stenting of the dorsal pancreatic duct without minor papillotomy in the treatment of acute recurrent pancreatitis and chronic pancreatitis.[71-73] Long-term resolution of acute recurrent pancreatitis with multiple exchanges of 5F to 7F stents was reported.[71,72] Dorsal duct stenting for chronic pancreatitis in pancreas divisum patients decreased pain in approximately half of patients in a small study.[73] There are no randomized trials comparing stenting with minor papillotomy in pancreas divisum.

Prevention of post-ERCP pancreatitis. Two large recent meta-analyses of 680 and 556 patients including 8 randomized, controlled trials showed a significant reduction in mild, moderate, and severe pancreatitis rates with placement of prophylactic pancreatic stents in high-risk patients (eg, ampullectomy, pancreatic sphincterotomy, precut sphincterotomy, sphincter of Oddi dysfunction, and difficult cannulations).[74,75] Most studies used small-diameter (3F-5F), short stents (3-5 cm) with only an external flap or pigtail.

Comparative studies

Plastic versus plastic stents. Multiple studies comparing different designs of plastic stents for the biliary tract have shown no consistent improvement in the duration of stent patency. An early study comparing Tannenbaum Teflon stents without side holes with a Teflon pigtail stent with side holes showed significantly longer patency with the Tannenbaum design stent.[76] However, 3 more recent studies showed no significant difference in stent patency for patients with malignant biliary obstruction between Tannenbaum stents and polyethylene stents with side holes.[77-79]

Three studies compared plastic stents with and without a hydrophilic polymer coating. Two studies showed no difference in stent patency,[80,81] whereas 1 study showed an increased stent patency of uncoated polyethylene stents compared with coated polyurethane stents (105 vs 77 days).[82]

A comparison of the Olympus DoubleLayer stent without side holes demonstrated improved patency compared with polyethylene stents with side holes.[83] DoubleLayer stents did not show increased patency when compared to Tannenbaum stents.[84]

Plastic versus metal stents. Four randomized, controlled studies compared the use of SEMSs versus plastic stents (REFS). In a meta-analysis that included these 4 studies, there was no difference between SEMSs and plastic stents with regard to technical or therapeutic success in draining the bile duct initially. However, SEMSs were found to have significantly less stent occlusion by 4 months and significantly reduced risk of recurrent biliary obstruction overall.[16-18,85,86]

Metal stents. Comparative retrospective studies of the management of occluded metal biliary stents have had mixed results. Two studies found no difference in stent patency if a plastic or metal stent was placed in the occluded metal stent.[87,88] Four studies showed increased patency with the placement of a second metal stent versus a plastic stent within the occluded stent. One study showed the highest patency rate with a covered SEMS placed in the occluded stent.[89-92]

Few comparative studies exist between different SEMSs. One study compared 6- and 10-mm Zilver stents with 10-mm Wallstents in extrahepatic biliary obstruction. The 10-mm Zilver stents and Wallstents had a similar percentage of stent occlusion, but the 6-mm Zilver stents had a significantly higher overall and significantly earlier occlusion rate.[93] Two studies compared nitinol and stainless steel SEMSs and found no difference in efficacy, stent patency, or adverse events.[94,95] One of these studies found that, on subgroup analysis, nitinol stents had a longer duration of stent patency for hilar tumors.[95]

Three multicenter randomized trials and a meta-analysis compared covered and uncovered SEMSs in the treatment of distal malignant biliary obstruction.[96-99] Two of the randomized trials found no difference in duration of stent patency,[96,97] whereas 1 trial showed significantly increased stent patency with covered SEMSs.[98] A meta-analysis that included these 3 studies and an additional 2 randomized trials of SEMSs placed percutaneously found covered metal stents to have significantly greater stent patency by more than 60 days, although covered SEMSs had higher stent migration, tumor overgrowth, and sludge formation.

Safety. *Biliary.* The 2 main adverse events with plastic biliary stents are migration and stent occlusion. Migration, predominantly distally, occurs in 5% to 10% of cases[100,101] and may rarely result in bowel obstruction, perforation, or fistula formation. Proximal migration is less commonly seen. Stent occlusion requiring reintervention can be as high as 30% to 40% with plastic stents and increases with increased stent indwelling time.[1,102] Cholangitis can also be a more immediate adverse event when adequate drainage is not achieved, especially in hilar tumors.[103] Increased rates of pancreatitis may occur with placement of larger (10F or larger) plastic stents, particularly when a sphincterotomy is not performed.[104,105]

Migration occurs much less frequently in uncovered SEMSs (<1%) because of the larger diameter and tissue growth between the interstices.[95] Metal stents develop stent occlusion at a significantly later date and with less frequency than plastic stents.[16-20] Pancreatitis rates with SEMS placement may be increased compared with plastic stents; there was no significant difference in pancreatitis risk between covered and uncovered SEMSs.[106]

Covered SEMSs have increased migration rates (3%-12%) compared with uncovered SEMSs.[96,97] Acute cholecystitis may occur in as many as 10% of patients with intact gallbladders after placement of a covered SEMS across the cystic duct.[96,97,107]

Pancreatic. The main adverse events of pancreatic stents include migration, stent occlusion, and stent-induced pancreatic ductal changes. Undesired stent migration occurs in 5.2% (proximal) and 7.5% (distal) of cases.[108] Because of the generally smaller diameter stents used in the pancreas, approximately 50% will be occluded by 4 weeks, with the majority occluded by 3 months.[45,46,109,110] Pancreatic ductal changes can occur in as many as 36% to 83% of ducts after stenting for as briefly as 2 to 3 weeks.[111,112] Ductal changes occur more frequently in patients with a normal pancreatogram before stenting and may be permanent in one third of cases. Pancreatitis was reported in 3% with removal of prophylactic pancreatic duct stents even without ERCP.[113]

Financial considerations

The prices of available plastic and biliary stents and SEMSs are listed in Tables 1 through 3. Most plastic stents can be purchased either separately or with an associated introducer catheter or pusher.

A specific code exists for ERCP with stent placement, CPT 43268. This code covers stent placement in either the bile or pancreatic duct. A separate CPT code exists for ERCP with stent removal or exchange, CPT 43269.

Multiple cost-effective comparisons have been made between SEMSs and plastic stents in the treatment of malignant biliary strictures with inconsistent results. One study found no difference in the cost of relieving malignant jaundice between SEMSs and plastic stents.[114] In a cost model of patients with malignant biliary strictures secondary to pancreatic cancer regardless of resectability, covered SEMSs were found to cost less than DoubleLayer or polyethylene stents.[115] Another modeling study for patients with unresectable pancreatic cancer showed that initial SEMS placement was more cost-effective than initial plastic stent placement, particularly in patients who survived longer than 6 months.[116] One study found Tannenbaum stents to be a cost–saving strategy compared with SEMSs for palliation in pancreatic cancer patients with biliary obstruction. This was particularly true with patients with liver metastases and expected short survival time.[117]

AREAS FOR FUTURE RESEARCH

Further investigation into how to increase the duration of patency of both plastic and metal stents is needed. In vivo studies of how to decrease bacterial adhesion and bacterial biofilm formation in plastic stents should be performed. Larger, randomized studies are needed comparing the safety, clinical effectiveness, and cost-effectiveness of the use of covered SEMSs versus plastic stents in the treatment of benign strictures. Small studies have shown that endoscopically-placed, drug-eluting SEMSs may improve stent patency and overall survival in cholangiocarcinoma. Further in vitro and in vivo studies are needed to determine the optimal drugs and drug delivery systems.[118-120] Biodegradable stents, which potentially do not require removal, are being developed and require further study.

SUMMARY

Biliary and pancreatic stents are used in a variety of benign and malignant conditions including strictures and leaks and in the prevention of post-ERCP pancreatitis. Both plastic and metal stents are safe, effective, and easy to use. SEMSs have traditionally been used for inoperable malignant disease. Covered SEMSs are now being evaluated for use in benign disease. Increasing the duration of patency of both plastic and metal stents remains an important area for future research.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviation: SEMS, self-expandable metal stent.

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