

## Fully covered self-expandable metal stents for treatment of malignant and benign biliary strictures

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### Abstract

**AIM:** To present a series of covered self-expandable metal stents (CSEMS) placed for different indications and to evaluate the effectiveness, complications and extractability of these devices.

**METHODS:** We therefore retrospectively reviewed the courses of patients who received CSEMS due to malignant as well as benign biliary strictures and post-sphincterotomy bleeding in our endoscopic unit between January 2010 and October 2011.

**RESULTS:** Twenty-six patients received 28 stents due to different indications (20 stents due to malignant biliary strictures, six stents due to benign biliary strictures and two stents due to post-sphincterotomy bleeding). Biliary obstruction was relieved in all cases, regardless of the underlying cause. Hemostasis could be achieved

in the two patients who received the stents for this purpose. Complications occurred in five patients (18%). Two patients (7%) developed cholecystitis, stents dislocated/migrated in other two patients (7%), and in one patient (3.6%) stent occlusion was documented during the study period. Seven stents were extracted endoscopically. Removal of stents was easily possible in all cases in which it was desired using standard forceps. Twelve patients underwent surgery with pylorus preserving duodenopancreatectomy. In all patients stents could be removed during the operation without difficulties.

**CONCLUSION:** Despite the higher costs of these devices, fully covered self-expanding metal stents may be suitable to relieve biliary obstruction due to bile duct stenosis, regardless of the underlying cause. CSEMS may also represent an effective treatment strategy of severe post-sphincterotomy bleeding, not controlled by other measures.

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**Key words:** Completely covered self-expandable metal stents; Pancreatic carcinoma; Biliary stenosis

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### INTRODUCTION

Recently, fully covered self-expandable metal stents

(CSEMS) have been lately used for the management of various malignant as well as non malignant biliary conditions, including strictures of the distal bile duct, anastomotic stenosis after orthotopic liver transplantation and post-sphincterotomy bleeding. We here report our experience using fully-CSEMS for these patients.

## MATERIALS AND METHODS

Between January 2010 and October 2011, 26 patients received 28 fully covered self-expanding metal stents (Wall-Flex RX, Boston Scientific) for various reasons. There were 20 patients with carcinoma of the pancreatic head, three patients with stenosis of the distal bile duct because of chronic pancreatitis (four stents), one patient with stenosis of the bile duct anastomosis following orthotopic liver transplantation (two stents) and two patients with severe bleeding following endoscopic sphincterotomy. The mean length of strictures was 20 mm. Depending on the type of stenosis a length of either 40 mm with 10 mm diameter (22 stents) or a length of 60 mm with 8 mm diameter (6 stents) was chosen. All stents were placed transpapillary by endoscopic retrograde cholangiography (ERC) following sphincterotomy and dilation of the stenosis with an 8.5 French rigid dilator (except for the patients with bleeding after sphincterotomy). Antibiotics were only administered if cholangitis was suspected. For sufficient bile flow, all patients were hydrated by administering 1000 mL of Ringer, lactate solution daily for 2 d peri-interventionally. All endoscopic procedures were performed by four interventional gastroenterologists.

## RESULTS

Twenty-six patients (8 male and 18 Female) received 28 fully covered self-expanding metal stents. The mean age of the patients was 58.5 years. In patients with pancreatic carcinoma, the procedure was performed within 2 d after admission if abdominal ultrasound or computed tomography showed biliary obstruction and/or laboratory tests indicated cholestasis. ERC and sphincterotomy and stent placement were successful at first attempt in all cases of pancreatic carcinoma. In the other six patients who received stents due to benign indications sphincterotomy had already been performed previously, and stent placement was technically feasible in all patients at first attempt. Drainage was achieved as monitored by a rapid decrease or normalization of bilirubin. In two patients, the stent was inserted because of severe bleeding following endoscopic sphincterotomy. This procedure led to an immediate pressure onto the bleeding area and made control of bleeding by injection of saline/epinephrine easy and safe.

No re-stenosis occurred during a follow-up period of 6 mo in two patients with distal bile duct stenosis due to chronic pancreatitis. The third patient underwent surgery as malignancy could not be excluded.

## Complications

In our series, five from 26 patients with 28 implanted stents (18%) developed complications.

Two patients developed cholecystitis (7%). In one of these patients the stent had to be removed as it blocked the cystic duct, in the second patient this complication could be managed by administration of antibiotics. In two patients (7%) in whom stents were implanted due to benign indications stent dislocation occurred. In one patient (anastomosis stenosis after orthotopic liver transplantation) the stent migrated distally, leading to cholestasis again. The stent was extracted and replaced by a longer one (6 cm). In another patient with distal bile duct stenosis due to chronic pancreatitis spontaneous dislocation of the stent occurred, which was not found on scheduled ERC done 6 mo after stent implantation. Stent occlusion occurred only in one patient (3.6%) with pancreatic carcinoma due to a bile duct stone previously not diagnosed.

## Removal of stents

Seven stents were removed endoscopically. Removal of stents was easily possible in all cases using standard forceps. The stents were removed after a mean time of 50 d (3-168 d).

The two patients with bleeding after sphincterotomy had their stents removed after 14 d. In the liver transplant patient with stenosis of the bile duct anastomosis, the first stent was found dislocated distally when scheduled ERC was preformed 6 wk after stent placement. The stent was removed from the distal bile duct and replaced with another stent, which was extracted 30 d later. No re-stenosis occurred since. In two patients with chronic pancreatitis the stents were removed after 82 d and 168 d respectively, there was no significant stenosis after removal of the stents and a wait and see policy was suggested. The third patient underwent resection of the pancreatic head as malignancy could not be excluded preoperatively, and the stent was removed during this procedure. In one patient with pancreatic carcinoma who developed acute cholecystitis after stent insertion, the stent was removed after 3 d.

Twelve patients with stenosis of the distal bile duct because of malignancy underwent surgery with pylorus preserving duodenopancreatectomy after a mean duration of 8 d following biliary drainage and complete staging of the tumor with computed tomography and sonography in all cases. In all patients stents could be removed during the operation without difficulties. Leakage of the biliodigestive anastomosis occurred in one patient (8.5%). This patient died due to a cause not related to the procedure (liver failure). Otherwise, no increased rate of complications or difficulties in creating an anastomosis with the remaining bile duct was reported by our surgeons. The median postoperative duration of hospitalization was 20 d. The eight patients with malignant stenosis of the bile duct who did not undergo an operation because of

far advanced disease were monitored on follow-up for a mean time of 64 d (30-75 d). Except for one patient with stent occlusion due to a bile duct stone previously not diagnosed no complications were documented.

## DISCUSSION

Our report shows that biliary drainage can be achieved using fully covered self-expanding metal stents regardless of the underlying disease, be it benign or malignant. Recent and our data suggest that CSEMS were not associated with a higher rate of complication compared to uncovered self-expanding metal stents or plastic stents. In contrast to the latter a much lower rate of occlusion and subsequent cholangitis was observed. This is in accordance with another recent report, in which the authors recommend fully covered self-expanding stents as the initial intervention for biliary obstruction even if the surgical respectability status is uncertain<sup>[1]</sup>. The internal diameter of 8 mm to 10 mm of these stents ascertains sufficient bile flow, if bile is very viscous because of previous biliary obstruction. We chose the length of the stent as short as possible to avoid any alteration of the proximal common bile duct. If surgery for the underlying disease was possible, no biliary leaks or complications of the biliary anastomosis were observed. In the patients in whom resection was not intended or could not be performed because of widespread or metastatic disease, stents remained in place on follow-up.

CSEMS intended initially to palliate malignant biliary obstruction, have been used recently in management of various benign biliary conditions and iatrogenic complications, as in post-sphincterotomy bleeding. In a case series including five patients, the use of CSEMS was effective to achieve hemostasis in all patients. However, migration of the stents occurred in two patients<sup>[2]</sup>. In the two patients described in our paper temporary placement of fully CSEMS was effective in controlling severe bleeding following endoscopic sphincterotomy, which could not be managed by other means. No stent dislocation occurred, as we removed the stents 2 wk after implantation. New development, like anchoring flap at the proximal end of the stent may be an option as well to prevent stent migration<sup>[3]</sup>.

So far, only plastic stents could be removed safely endoscopically if necessary. The disadvantage of these stents, however, is the small internal diameter which predisposes to occlusion by biliary sludge. On the other hand, self-expanding metal stents resulted in efficient drainage of biliary obstruction with good bile flow due to the large diameter in contrast to plastic stents. The big drawback of self-expanding metal stents, nevertheless, was that they could not be extracted easily, if at all. With the availability of fully covered self-expanding stents this short coming has been overcome.

In a multicenter study, including 37 patients removal attempts of the CSEMS were successful in all cases<sup>[4]</sup>. The endoscopic feasibility and safety of stent removal

were also documented by other authors<sup>[5]</sup>. In our series endoscopic removal of the stents was feasible and safe in all patients, in whom stent explanation was desired.

We observed cholecystitis in two patients. In both patients, the outlet of the cystic duct into the common bile duct was blocked by the stent. Although the numbers are small, we suggest that this complication should be avoided by using a stent length with the upper end distal to the cystic duct outlet. In one study, this complication occurred in 20% of cases if the CSEMS covered the cystic duct. A gallbladder stent (seven French transpapillary pigtail gallbladder stent) was effective in reducing the risk of developing cholecystitis after CSEMS placement<sup>[6]</sup>.

Despite the higher costs of these devices, fully CSEMS may be suitable to relieve biliary obstruction due to bile duct stenosis, regardless of the underlying cause. They can easily be extracted and do not increase complications following bile duct anastomosis in surgical tumor resection. CSEMS may be also an effective treatment option in severe post-sphincterotomy bleeding, not controlled by other measures.

## COMMENTS

### Background

Transpapillary stents are used to treat biliary strictures, whether benign or malignant. However, there are different stent types and data are controversial. Recently, completely covered self-expandable metal stents (CSEMS) have become available.

### Research frontiers

The aim of this study is to present a series of CSEMS placed for different indications and to evaluate the effectiveness, complications and extractability of these devices.

### Innovations and breakthroughs

CSEMS intended initially to palliate malignant biliary obstruction, have been used recently in management of various benign biliary conditions and iatrogenic complications. The internal diameter of 8 to 10 mm of these stents ascertains sufficient bile flow, if bile is very viscous because of previous biliary obstruction. So far, only plastic stents could be removed safely endoscopically if necessary. The disadvantage of these stents, however, is the small internal diameter which predisposes to occlusion by biliary sludge. CSEMS can be easily removed endoscopically in almost all patients, in whom stent explanation is desired.

### Applications

Fully CSEMS may be suitable to relieve biliary obstruction due to bile duct stenosis, regardless of the underlying cause.

### Terminology

CSEMS: completely covered self-expandable metal stent is a metallic tube used to hold open the biliary passages. The most common indication of this device is to alleviate symptoms caused by biliary tract obstruction due to various benign and malignant conditions. The stent is inserted under fluoroscopic and endoscopic control.

### Peer review

This paper adds to a growing literature demonstrating the feasibility, ease, and safety of CSEMS for malignant and benign strictures.

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