

Gallbladder Stent Placement for Prevention of Cholecystitis in Patients Receiving Covered Metal Stent for Malignant Obstructive Jaundice: A Feasibility Study

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Abstract

Purpose Covered self-expanding metal stents (CSEMS) have been used for palliation of malignant distal biliary strictures. Occlusion of the cystic duct by CSEMS may be complicated by cholecystitis. This potentially could be prevented by placement of a transpapillary gallbladder stent (GBS).

Patients and Methods Between 11/2006 and 10/2007, a total of 73 patients (50 male) aged 65 ± 14 years underwent CSEMS placement for palliation of malignant obstructive jaundice. In cases where CSEMS placement caused occlusion of the cystic duct, a 7 French transpapillary pigtail gallbladder stent (GBS) was inserted to prevent cholecystitis.

Results Of the 73 patients, 18 had a prior cholecystectomy; 34 had the CSEMS placed below the cystic duct insertion. In 19 out of the 21 patients who had a CSEMS covering the cystic duct ostium, GBS placement was attempted, which was successful in 11 individuals (58%). An attempt to access the gallbladder was complicated by wire perforation of the cystic duct in three patients; one patient requiring emergent cholecystostomy tube placement. None of the patients who underwent successful GBS placement developed cholecystitis. One GBS dislodged and was repositioned. Cholecystitis occurred in two (20%) of

the ten patients without transpapillary gallbladder decompression who had a CSEMS covering the cystic duct.

Conclusions The ideal placement of a CSEMS is below the cystic duct insertion. Should the cystic duct ostium be occluded, placement of a GBS should be considered to minimize the risk of cholecystitis.

Keywords Gallbladder stent · Cholecystitis · Bile duct stricture · Pancreatic cancer

Introduction

Malignancies of the pancreatic head, duodenum, or distal bile duct carry a poor prognosis [1]. Although new chemotherapeutic agents have a positive effect on the course of these cancers, the outcome is still dismal [2, 3]. The majority of cases are diagnosed at an advanced stage, making palliation the focus of most interventions. Obstructive jaundice with eventual gastric outlet obstruction are the major presenting symptoms in these patients. Therefore, for decades, the surgical strategy consisted of a combination of gastrojejunostomy and hepaticojejunostomy [4–6]. However, these surgical procedures carry a significant morbidity and therefore, less-invasive interventions have been offered on a daily basis. Endoscopic stenting has become standard practice for palliation in patients with inoperable malignant biliary obstruction [7–9]. Self-expanding metallic stents (SEMS) are preferred for palliation of malignant obstructive jaundice due to prolonged patency rates when compared to plastic stents [10–12]. One of the major limitations of SEMS is their occlusion by tumor progression through the uncovered meshes. Covered SEMS (CSEMS) were thus created to prevent tumor ingrowth, but have not clearly shown superiority to uncovered SEMS

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[13, 14]. Complications of CSEMS include stent migration, occlusion, post-ERCP pancreatitis, and cholecystitis [15–17]. Cholecystitis is a rare complication after placement of plastic or uncovered metallic stents [11, 12]. Rates of cholecystitis after placement of CSEMS have been as high as 12% [18]. This is felt to be secondary to occlusion of the cystic duct and stasis related to the covered portion of the stent [15, 16]. This complication is typically managed with cholecystectomy or placement of a cholecystostomy tube. Placement of transpapillary gallbladder stent (GBS) has been previously reported in patients with gallbladder cancer and acute cholecystitis [19–24]; however, not in the setting of bile duct stenting for distal biliary obstruction.

In the present study, we analyzed the feasibility, efficacy, and morbidity of transpapillary GBS in the prevention of cholecystitis in patients who underwent CSEMS placement for neoplastic distal biliary obstruction.

Patients and Methods

Between November 2006 and October 2007, 73 patients (50 male, 23 female) aged 65 ± 14 years underwent CSEMS placement for distal malignant biliary obstruction (Fig. 1). In 18 patients, the gallbladder was absent; in 34 the CSEMS was placed below the cystic duct insertion. In the remaining 21 patients, the CSEMS was occluding the cystic duct ostium and GBS placement was attempted in 19 patients, the two remaining patients had a collapsed gallbladder.

Materials

All procedures were performed under general anesthesia. Side-viewing endoscopes (TJF-140 or TJF-160; Olympus America, Center Valley, PA) were used for ERCP. CSEMS

placed were 10-mm-diameter Wallstent (Boston Scientific, Natick, MA); or VIABIL (Conmed, Utica, NY).

Technique

ERCP was performed using conventional techniques. Following biliary sphincterotomy, a cholangiogram was performed to determine the length of each stricture and the origin of the cystic duct insertion in patients with an intact gallbladder. The proximal CSEMS delivery system was advanced above the stricture over a guidewire where the CSEMS was partially deployed and positioned within the stricture before complete deployment. In cases where the gallbladder was present, CSEMS were positioned below the cystic duct insertion whenever possible (Fig. 2). In cases where the cystic duct insertion would be covered by the CSEMS, wire access of the gallbladder was obtained (Fig. 3) and a 7 French single pigtail plastic stent was then inserted into the gallbladder in a transpapillary fashion for decompression, prior to placement of the CSEMS (Figs. 4 and 5). In difficult cases, access into the gallbladder through the cystic duct was typically achieved using a sphincterotome as a steering catheter preloaded with a guidewire.

Definition of Events

Successful CSEMS placement was defined as biliary decompression post-CSEMS deployment with relief of jaundice, pruritus, and/or cholestasis. Successful gallbladder stenting was defined as successful deployment of a gallbladder stent without any complications. A diagnosis of cholecystitis was made in patients who presented with right upper quadrant and/or epigastric pain, associated with radiologic evidence of cholecystitis on ultrasound or CT

Fig. 1 Outcome of patients receiving CSEMS with or without gallbladder stenting. CSEMS covered self-expanding metal stents, CCY cholecystectomy, GBS gallbladder stent

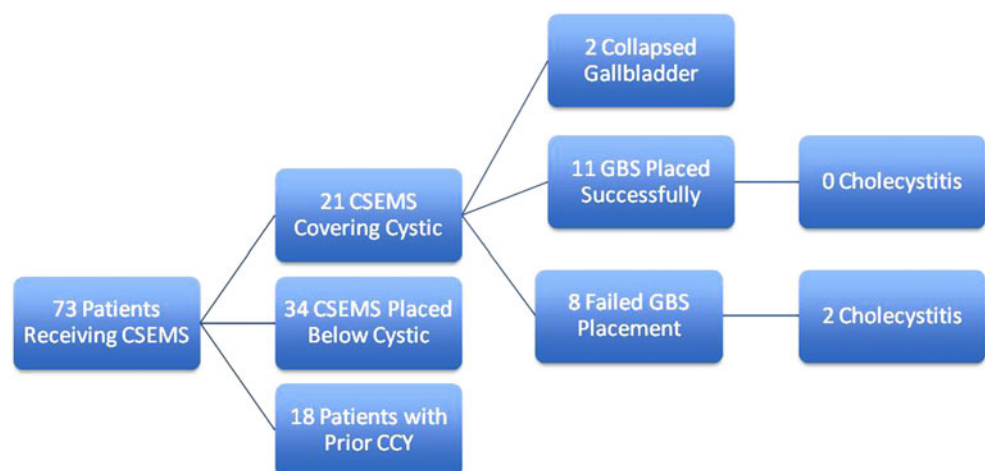




Fig. 2 Fluoroscopic images of a CSEMS deployed below the cystic duct insertion

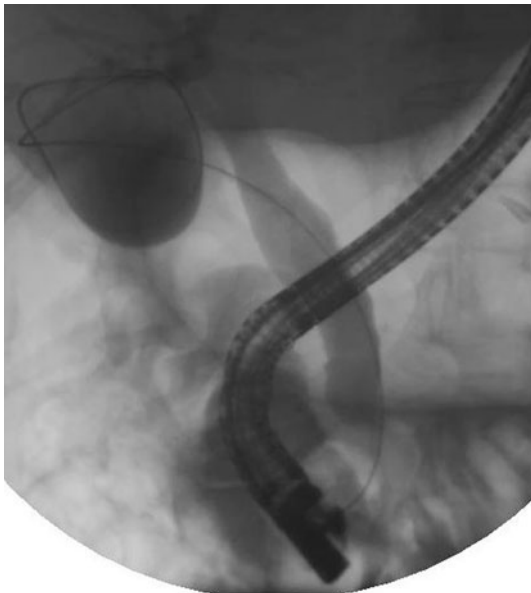


Fig. 3 Access to the gallbladder through the cystic duct with a guidewire

imaging, and was confirmed by pathology whenever surgical cholecystectomy was performed. Repeat intervention was defined as the need for endoscopic, percutaneous, or surgical procedures to improve biliary or gallbladder drainage after the original procedure.

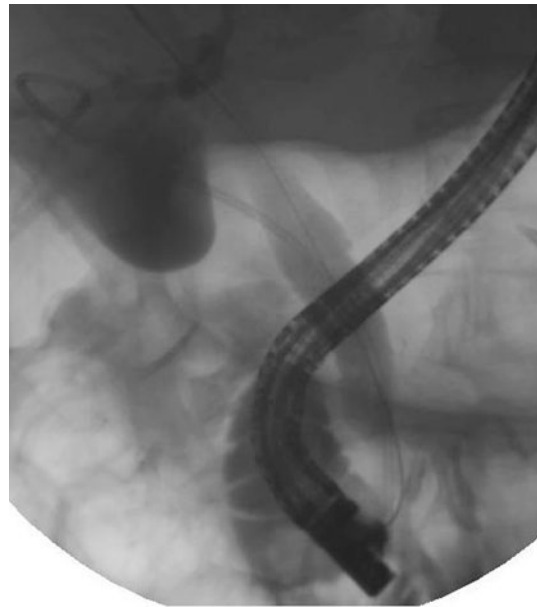


Fig. 4 Deployment of a 7 French single pigtail stent in the gallbladder after securing access to the bile duct with a guidewire

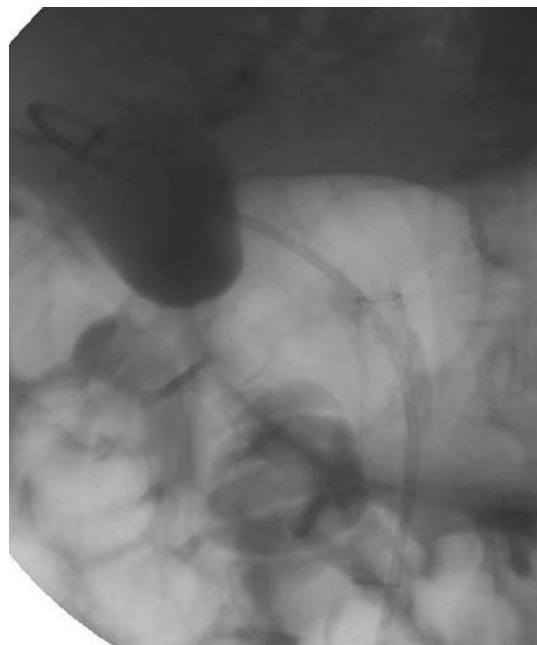


Fig. 5 Deployment of CSEMS along side the 7 Fr gallbladder stent

Patient Follow-Up and Statistics

Patients were followed prospectively until surgical intervention, death, stent dysfunction, or as clinically indicated. Baseline demographics, complications, clinical response to therapy, procedure-related morbidity, and symptoms were recorded. Success was defined as persistent biliary decompression without development of cholecystitis. The study was approved by our IRB; all patients provided written

consent for their procedures. The level of significance was set at $P < 0.05$ for statistical analyses.

Results

Out of the 21 patients who had a CSEMS placed that covered the cystic duct insertion, the gallbladder was collapsed in 2/21 and therefore no GBS was placed. Transpapillary GBS was attempted in the remaining 19 individuals and was successfully placed without complication in 11 patients (58%). In the eight unsuccessful cases, technical problems accessing the cystic duct were responsible for failure in five cases. Wire perforation of the cystic duct occurred in three patients during the procedure. Two of these patients were successfully managed conservatively, and one required emergent cholecystostomy tube placement.

The 11 patients who had successful GBS placement included seven men and four women with a median age of 68 (range 49–96) years (Table 1). Demographic and clinical data are shown in Table 1. Underlying diseases included pancreatic cancer ($n = 7$), duodenal cancer ($n = 1$), ampullary cancer ($n = 1$), ampullary adenoma with high-grade dysplasia in a patient with Gardner syndrome ($n = 1$), and metastatic adenocarcinoma of undetermined origin ($n = 1$). The presenting symptom was jaundice ($n = 6$) and cholangitis ($n = 2$). Three patients had tumors that were incidentally found on radiologic imaging.

None of the 11 patients developed immediate post-interventional complications such as bleeding, pancreatitis, or cholangitis. Additionally, no patients undergoing GBS placement developed cholecystitis during a median follow-up of 135 (20–389) days. Two GBS were removed during curative surgery. One GBS migrated proximally into the common bile duct after 2 months causing cholangitis; the GBS was successfully repositioned during repeat ERCP.

Table 1 Characteristics of patients with gallbladder in place

Number of patients	11
Mean age y/o \pm SD (range)	66 \pm 9 (49–81)
Diagnosis	Pancreatic cancer ($n = 7$) Duodenal cancer ($n = 1$) Ampullary cancer ($n = 1$) High grade dysplasia ($n = 1$) Metastatic adenocarcinoma ($n = 1$)
Mean months follow-up (range)	7 \pm 4 (2–12)
Final outcome	3 still alive 8 expired from tumor progression

After a median follow-up of 270 (range 72–734) days, three patients were alive and eight had died secondary to cancer progression. One patient is alive with advanced cancer (after 16 months) and two are in remission at 15 and 25 months, respectively. Cholecystitis occurred in two (20%) of the ten patients without transpapillary gallbladder decompression who had a CSEMS covering the cystic duct. There was no statistical difference in terms of age, gender, diagnosis and complication rate between the two groups.

Discussion

Biliary stent placement for malignant obstruction is now a common palliative procedure with innovation aimed towards improving the efficacy of such stents [4, 25, 26]. Multiple studies have been published over the years heralding the use of metallic biliary stents over their plastic counterparts [10, 25–29]. More recently, covered metallic stents have taken center stage in an attempt to prevent tumor ingrowth [30], although more recent studies have been unable to confirm their superiority to uncovered SEMS [13, 14, 31]. Covered metallic stents may have their own set of complications, which include migration, occlusion, post-ERCP pancreatitis, and cholecystitis in up to 10% of cases [16]. This is a substantially increased rate when compared to rates of cholecystitis reported in plastic and uncovered metallic stents, which were 0–1.6% [15, 16]. In the study by Fumex et al. [18], the development of cholecystitis was independent of tumor involvement in the cystic duct. Cholecystitis developed as an early complication in most of these cases secondary to occlusion of the cystic duct orifice by the stent itself. Identified risk factors from a multivariate analysis done by Suk et al. [16] include obstruction of the cystic duct and presence of gallbladder stones. This is in contrast to the study of Isayama et al. [15], in which the only independent predictor for development of cholecystitis after metal stent placement was tumor involvement of the orifice of the cystic duct. Deployment of CSEMS below the orifice of the cystic duct seems therefore to be the most appropriate intervention [31]. However, this is not always feasible, as the cystic duct insertion may be more distal or may be contained into the malignant stricture.

In prior studies, the risk of cholecystitis has been presented as a major drawback to the use of CSEMS. Options for management of acute cholecystitis in such settings include cholecystectomy or percutaneous drainage. Percutaneous cholecystostomy has been associated with a complication rate of 12.6%. Endoscopically performed retrograde cystic duct stent placement is an alternative to percutaneous cystic duct draining in poor surgical candidates. It has previously been described as an alternative to

percutaneous cholecystostomy in cirrhotic populations [20, 24]. In one study, 23 cirrhotic patients with symptomatic biliary colic, acalculous cholecystitis or acute calculous cholecystitis underwent endoscopic gallbladder stent placement. Presenting symptoms resolved in all patients and lasted as long as 3 years post-procedure [20]. The success of such stenting in cirrhotic patients supports its potential utility in preventing cholecystitis in patients undergoing CSEMS for obstructive distal biliary neoplasia. In the present study, transpapillary stenting of the cystic duct was attempted in cases where CSEMS placement for malignant biliary obstruction would occlude the cystic duct orifice and was successful in the majority of patients; interestingly, none of the patients with a gallbladder stent placed developed cholecystitis, and this after a follow-up time of up to 25 months. Only one patient out of the three who developed wire perforation of the cystic duct required emergent cholecystotomy, which was inevitable since the patient presented with signs of cholecystitis. On the other hand, two out of the eight (25%) patients who had unsuccessful transpapillary gallbladder decompression with CSEMS covering the cystic duct developed cholecystitis. The risk associated with attempting gallbladder stenting seems to be offset by the long-term benefit provided, it remains however, a challenging procedure eventually associated with cystic duct perforation. The other alternative would be to place an uncovered metal stent, since most recent studies were unable to demonstrate superiority of CSEMS when compared to uncovered metal stents [13, 14]. Until a randomized trial comparing those two options is performed, both alternative should be left at the discretion of the endoscopist.

In conclusion, if CSEMS placement is chosen, it should be ideally deployed distal to the cystic duct insertion. In cases where this is not feasible, an attempt at GBS placement should be considered to minimize the potential for development of cholecystitis.

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