

# Endoscopic stenting for malignant biliary obstruction is technically successful in patients with preexisting duodenal stents



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## ABSTRACT

**Background and study aims** There are limited data on the success of endoscopic retrograde cholangiopancreatography (ERCP) in patients with malignant biliary and duodenal obstruction with a preexisting duodenal stent. The aim of this study was to evaluate patient and procedural outcomes of a cohort of patients with preexisting duodenal stents who underwent an attempt at ERCP for malignant biliary obstruction (MBO).

**Patients and methods** This was a single-center retrospective study on consecutive patients with a preexisting duodenal stent who underwent attempted ERCP for MBO. Technical success was defined as successful cannulation of the common bile duct, with successful dilation and/or deployment of a biliary stent under fluoroscopy. Clinical success was defined as number of patients in the entire group who underwent ERCP successfully with resolution of symptoms.

**Results** We identified 64 patients (73% men, 74% white, median age 62 years) with a preexisting duodenal stent who underwent 85 attempts at ERCP. ERCP was technically successful in 50 of 85 procedures (59%). Overall ERCP was successful in 41 of 85 patients (48%). ERCP was more likely to be successful in patients with Type 1 and 3 duodenal strictures than with Type 2 strictures (83% and 92% vs. 42%,  $P<0.01$ ), in patients with a preexisting sphincterotomy (79% vs. 20%,  $P=0.01$ ) or preexisting biliary stent (66% vs. 34%,  $P=0.04$ ). Adverse events included bleeding ( $n=3$ ), post-procedure fever ( $n=3$ ) and abdominal pain ( $n=1$ ).

**Conclusions** Although biliary stenting via ERCP is often technically challenging in patients with a prior duodenal stent, it is a safe and effective method of biliary drainage. ERCP should be attempted in patients with Type 1 and 3 duodenal strictures, a prior sphincterotomy or an indwelling biliary stent.

## Introduction

Malignant duodenal and malignant biliary obstruction (MBO) may occur concurrently in patients with pancreatic, gastric, and duodenal cancers when the tumor involves the periampul-

lary region of the duodenum. When a duodenal stent is placed across the papilla for palliation of duodenal obstruction, subsequent endoscopic retrograde cholangiopancreatography (ERCP) may become technically challenging. Biliary drainage in

these patients may be attempted via the transpapillary route, percutaneously or with endoscopic ultrasound (EUS) guidance.

Prior retrospective studies have reported transpapillary stenting through the existing duodenal stent, with success rates ranging from 34% to 87% [1–5]. However, because all these studies had small numbers of patients, data on the technical success of ERCP in patients with concomitant duodenal obstruction with a preexisting duodenal stent across the papilla are limited. We aimed to determine the success of endoscopic transpapillary biliary drainage via ERCP, in patients with MBO with a preexisting duodenal stent.

## Patients and methods

This was a retrospective review of all patients at a large tertiary cancer center with a preexisting duodenal stent who underwent endoscopic biliary drainage via ERCP for MBO.

### Patient identification

We identified consecutive patients who underwent duodenal stent insertion from July 2007 to November 2017 using Current Procedural Terminology (CPT) codes for upper endoscopy with duodenal stent insertion. We then identified patients who underwent attempted ERCP on a date after duodenal stent insertion by using CPT codes for ERCP. We excluded patients with biliary obstruction above the hilum that were not considered candidates for ERCP.

Data were collected on demographics, type of malignancy, procedure date and details, type and length of biliary and duodenal stents, indication for procedures, symptoms, reinterventions, adverse events (AEs), length of hospital stay, and follow-up information including date of death or last follow-up.

Technically successful ERCP was defined as ERCP with successful cannulation of the common bile duct with successful dilation and/or deployment of a biliary stent under fluoroscopy, if clinically indicated. Clinical success was defined as number of patients in the entire group with resolution of symptoms of biliary obstruction (i.e., jaundice or cholangitis). If the indication for the procedure was biliary ductal dilatation observed on imaging, resolution of this finding was considered clinical success. AEs were graded as described by Cotton et al [6].

### Duodenal obstruction

Duodenal obstruction was determined by clinical symptoms and radiographic confirmation using multi-dimensional computed tomography scans. Patients then underwent upper endoscopy using Olympus therapeutic gastroscope (GIF-1T140, GIF-1TQ160, GIF-1TQ 180 Olympus, Central Valley, Pennsylvania, United States) with deployment of an uncovered metal Wallflex duodenal stent (Boston Scientific, Massachusetts, United States) across the area of duodenal stenosis.

Duodenal strictures were classified as by Mutignani et al [4]. Type 1 duodenal strictures were defined as strictures in the duodenal bulb or second part of the duodenum, proximal to the papilla, Type 2 duodenal strictures were defined as strictures in the second part of the duodenum involving the papilla

and Type 3 duodenal strictures were defined as strictures in the third part of the duodenum distal to the papilla.

### Biliary obstruction

Biliary obstruction was determined by onset of obstructive jaundice or ascending cholangitis and/ or CT imaging showing biliary duct dilation.

Patients then underwent ERCP using Olympus duodenoscope (TJF-Q160-180, Olympus, Central Valley, Pennsylvania, United States) with deployment of a covered or uncovered metal Wallstent (Boston Scientific, Massachusetts, United States) or a plastic Cotton-Leung stent (Cook Endoscopy, Winston-Salem, North Carolina, United States) across the biliary stricture under fluoroscopic guidance, if indicated. All endoscopic procedures were performed under general anesthesia or monitored anesthesia care using propofol.

### Statistical analysis

Patient characteristics were summarized using median and ranges for continuous variables and using frequencies and percentages for categorical variables.  $P < 0.05$  was considered statistically significant. All statistical analysis was carried out using SAS statistical software. The Memorial Sloan Kettering Cancer Center Institutional Review Board-approved the study.

## Results

### Patient characteristics

We identified 64 patients (73% men, 74% white) who underwent 85 attempts at ERCP after duodenal stent. Median age was 62 years (range 30–86). Each patient underwent an average of one procedure (range 1–5). Thirteen patients had more than one ERCP post duodenal stent insertion; nine of these had more than one clinically successful ERCP; five patients had more than three successful ERCPs each. Four patients had an initial successful post duodenal stent ERCP; however, the second attempt at ERCP was unsuccessful and they subsequently underwent percutaneous transhepatic biliary drainage (PTBD). In this group of 13 patients who had more than one post-duodenal stent ERCP, there were no significant differences between those who had a second or subsequent successful vs. unsuccessful ERCPs.

Patients had malignant duodenal and biliary obstruction from pancreas cancer ( $n=49$ ), gastric or duodenal cancer ( $n=4$ ), biliary cancer ( $n=2$ ) and metastatic cancer ( $n=9$ ). Type 2 duodenal strictures were most common ( $n=54$ ). Six patients had two coaxial duodenal stents in place prior to the attempted ERCP. The most common indication for biliary drainage was cholangitis ( $n=50$ ), followed by obstructive jaundice ( $n=31$ ) and dilated bile ducts on imaging ( $n=4$ ). Average time from duodenal stent to the first ERCP attempted after was 204 days (range 1–995 days).

### Procedure outcomes

ERCP post-duodenal stent was technically successful in 50 of 85 procedures (59%). Overall ERCP was successful in 41 of 85 patients (48%), i.e., 48% of patients had either clinical or radio-

► **Table 1** Characteristics of patients who underwent attempted ERCP after duodenal stent.

	Successful (n = 50)	Unsuccessful (n = 35)	P
Age (SD)	62 (13.2)	59 (12.4)	0.24
Male, n (%)	36 (72)	26 (74.3)	0.82
Race			0.01
▪ White	37 (74)	26 (74.3)	
▪ Black	6 (12)	4 (11.4)	
▪ Other	7 (14)	5 (13.8)	
Primary malignancy, pancreas, n (%)	36 (72)	24 (68.6)	0.73
Location of duodenal stricture			<0.01
▪ 1	15 (30)	3 (8.8)	
▪ 2	23 (46)	31 (88.2)	
▪ 3	12 (24)	1 (2.9)	
Preexisting biliary stent, n (%)	39 (78)	20 (57)	0.04
Preexisting sphincterotomy, n (%)	23 (46)	6 (17)	0.01
Indication for biliary drainage, n (%)			0.3
Abnormal CT findings	3 (6)	1 (2.9)	
Cholangitis	32 (64)	18 (51.4)	
Obstructive jaundice	15 (30)	16 (45.7)	
Duration of procedure in minutes, mean (SD)	55 (28)	40.1 (20.3)	0.001
Any adverse events	7 (14)	3 (8.5)	0.45
Months between duodenal stent and attempted ERCP Median (IQR) (SD)	3.5 (1–13)	2 (0–4)	0.009
Median survival in months Median (IQR)	12 (8–21)	9 (4–35)	0.01

ERCP, endoscopic retrograde cholangiopancreatography; SD, standard deviation; CT, computed tomography; IQR, interquartile range; LOS, length of hospital stay.

logical improvement after ERCP. A 9 cm x 22 mm uncovered duodenal stent was used in 50 cases (59%). A preexisting biliary stent was present prior to duodenal stent insertion in 61 of 85 procedures (72%). These patients had developed biliary obstruction prior to duodenal stent insertion and had undergone ERCP with biliary stent insertion for this reason.

ERCP was more likely to be successful in patients with Type 1 and 3 duodenal strictures than with Type 2 strictures (83% and 92% vs. 42%,  $P < 0.01$ ) and in patients with a preexisting sphincterotomy (79% vs. 20%,  $P = 0.01$ ) or preexisting biliary stent (66% vs. 34%,  $P = 0.04$ ) in place. Average duration of a successful procedure was 55 minutes (range 28–102). Average duration of unsuccessful procedure was 40 minutes (range 12–92). Argon plasma coagulation at 90 watts/1 L/min was used to cut through the mesh of the duodenal stent prior to bile duct cannulation in 10 cases. The median time interval between duodenal stent insertion and attempted ERCP was 3.5 months (range 1–13) vs. 2 months (range 0–4),  $P = 0.009$  in the successful vs. unsuccessful group.

Characteristics of successful and unsuccessful procedures are shown in ► **Table 1**.

Reasons for unsuccessful ERCP in 35 cases included inability to cannulate the common bile duct (48%), inability to traverse the duodenal stent (35%), and inability to deploy a stent within the bile duct after successful cannulation (17%). Of the 35 patients with unsuccessful ERCPs, 28 underwent percutaneous biliary drainage by interventional radiology (PTBD) and one patient underwent successful EUS-guided biliary drainage. Six patients did not undergo biliary drainage; four transitioned to hospice and two improved with continued intravenous (IV) antibiotics.

### Adverse events

Seven (14%) AEs occurred among patients who underwent ERCP successfully. These included bleeding ( $n = 3$ ), post-procedure fever ( $n = 3$ ) and severe post-procedure abdominal pain requiring IV opioids ( $n = 1$ ). All AEs were graded as mild to moderate.

## Patient outcomes

Eleven patients required delayed endoscopic biliary drainage after the initial successful ERCP. The most common indications were recurrent ascending cholangitis and stent obstruction without cholangitis. Median time to first reintervention for repeat biliary drainage was 141 days (85.7). Median survival after initial duodenal stent insertion was 12 months (range 8–21).

## Discussion

MBO and duodenal obstruction are often seen as complications of pancreatic, duodenal or metastatic cancers. Dorman et al reported as many as 60% of patients with advanced gastroduodenal and pancreatic malignancies develop biliary obstruction after duodenal obstruction, and thus, may already have a duodenal stent in place [7]. Our study represents the largest single-center cohort of patients with malignant biliary and duodenal obstruction in which transpapillary biliary stenting was attempted, in the presence of a preexisting duodenal stent. We successfully achieved biliary drainage via ERCP in almost two-thirds of these patients, with a technical success rate of 59%, clinical success rate of 48%, and complication rate of 12%.

Technical success of stenting was 42% in patients with Type 2 strictures but was much higher among those with Type 1 or Type 3 strictures at 82% and 93%, respectively. The technical success rate for transpapillary stenting in patients with a prior duodenal stent is reported between 34% and 100% [4, 5, 8], depending on the location of the duodenal stricture. It is least likely to be successful in patients with Type 2 duodenal strictures. Khasab et al. reported a 34% technical success [5] and Kentaro et al. reported a 23% technical success with biliary stenting in patients with Type 2 duodenal strictures [9], with an indwelling gastroduodenal stent that overlay the papilla, which was similar to the 42% success rate in our subset of patients with Type 2 strictures in our study. Type 2 duodenal strictures are technically challenging because the duodenal stent overlies the papilla, making it harder to visualize, and it leaves less room to maneuver the duodenoscope, making it harder to cannulate the papilla during subsequent ERCP.

In patients for whom transpapillary stenting is not possible, EUS-guided biliary drainage (EUS-BD) has been attempted as a salvage procedure, with technical success ranging from 90% to 100% [10–15]. However, EUS-BD, whether attempted by transluminal or rendezvous route, is associated with complication rates ranging from 10% to 43% [9–13, 16], even in expert hands. AEs include bleeding, cholangitis, peritonitis, bile leak, pancreatitis, cholecystitis, and stent migration, many of which are severe and may require repeat endoscopic or surgical intervention. Percutaneous biliary drainage is usually successful, but is also associated with complications, including catheter site leakage and pain, infection risk, and need for frequent repeat interventions [10, 15]. Our complication rate of 12% is lower than most reported complication rates for EUS-BD and percutaneous biliary drainage. The most common AEs in our patient group were bleeding and fever, which were self-limited and rarely required repeat endoscopic or radiologic intervention.

A study by Khasab et al. reported the average hospital stay was 4.7 days and average procedure duration was 87 minutes [5] for patients with MBO and duodenal obstruction undergoing EUS drainage as the primary source of drainage, which were longer than we observed. The population of patients undergoing these procedures have advanced cancer and are usually classified as American Society of Anesthesiologists class 3–4, in whom shorter procedure duration and anesthesia time are preferred.

A recent study by Matsumoto et al. in patients with both duodenal and biliary stents reported 26% and 41% biliary stent dysfunction rates at 3 and 6 months, respectively, which was like the reintervention rate we reported [7]. Tumor ingrowth into the biliary stent, causing recurrent biliary obstruction and/or cholangitis, was the most likely cause of stent dysfunction in these patients. Biliary stent dysfunction was also associated with duodenal stent dysfunction, and a subsequent study found that use of covered duodenal stents decreased the rate of biliary stent dysfunction [17, 18]. Unfortunately, these covered duodenal stents are not available in the United States. Notably, in our study, the time interval between initial duodenal stent insertion and attempted ERCP was actually longer in the group that successfully underwent biliary drainage via ERCP (3.5 vs. 2 months,  $P=0.009$ ), indicating that duodenal stent was not the cause of biliary stent dysfunction.

## Limitations

This study has a few limitations which should be noted. It was retrospective and has limitations inherent to retrospective studies. Second, selection bias exists as CT scans of all patients were carefully reviewed by expert radiologists and experienced clinicians, and only those patients with low biliary obstruction deemed amenable to endoscopic drainage underwent ERCP. All ERCP procedures were performed by experienced endoscopists, and the results may not be easily generalizable.

## Conclusions

This is the largest retrospective series to evaluate the efficacy of transpapillary biliary drainage in patients with a prior duodenal stent. Although transpapillary biliary stenting via ERCP is often technically challenging in patients with a prior duodenal stent, it is a safe and effective method of biliary drainage in patients with Type 1 or 3 duodenal strictures, with lower complication rates than EUS-BD. ERCP, therefore, should be considered as the initial modality in selected patients who develop MBO, especially in those with Type 1 or 3 duodenal strictures, a preexisting sphincterotomy, or a preexisting biliary stent.

## Competing interests

The authors declare that they have no conflict of interest.

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