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Biliary sphincterotomy is not required for bile duct stent placement

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Abstract

Background—The aim of the present study was to assess the success and outcome of bile duct stent placement without the use of endoscopic biliary sphincterotomy (EBS).

Patients and Methods—Over a period of 10 years and 9 months, all patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) were prospectively identified. Bile duct stent placement was routinely done without EBS unless additional therapy (stone removal, multiple stenting) was anticipated.

Results—Of 5020 patients who underwent ERCP, bile duct stents were placed in 1668 patients. After excluding those requiring additional endoscopic therapy, 1112 patients (89.5%) had ERCP and stent placement without a sphincterotomy and 130 patients (10.5%) had ERCP and stent placement with a sphincterotomy. Deployed endoprotheses were self-expandable metallic stents in 15.7% and plastic in 77.5%. Caliber of plastic stents was 10 Fr in 78.9% and <10 Fr in 21.1%. All stents were successfully placed in these 1112 patients without the need for EBS. Comparing patients undergoing bile duct stenting with and without sphincterotomy, no difference was seen in rates of pancreatitis (1.54% vs 2.07%, $P > 0.9999$).

Conclusion—Single bile duct stents, both plastic and metal, can be deployed without EBS.

Keywords

bile duct stent; endoscopic biliary sphincterotomy (EBS); endoscopic retrograde cholangiopancreatography (ERCP); jaundice; pancreatitis

INTRODUCTION

Over the last two decades, endoscopic retrograde cholangiopancreatography (ERCP) has evolved from a diagnostic to a therapeutic procedure. To provide access to the biliary system for therapy, endoscopic biliary sphincterotomy (EBS) is typically carried out. EBS is essential for removing large-caliber bile duct stones; however, there has been less critical

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CONFLICT OF INTERESTS

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study of its use for bile duct stent placement.^{1–3} While there have been two randomized studies^{1,2} suggesting that biliary stenting can be carried out without EBS in patients with malignant obstruction, in our experience, many endoscopists continue to carry out EBS prior to stent insertion regardless of indication. The genesis of the common practice of EBS before stent placement is unknown but may stem from prior studies suggesting that, at least for longer stents, the rate of post-ERCP pancreatitis may be lower if EBS is carried out⁴ or EBS perhaps makes stent placement easier. Although generally safe, EBS may pose several risks, particularly bleeding, which occurs in approximately 1.2% and can be life-threatening.⁵

Our practice has been to avoid EBS for bile duct stent placement unless additional endoscopic therapies mandating EBS are anticipated. In the present study, we report our large experience of bile duct stent placement without biliary sphincterotomy to underscore the feasibility of stent placement without EBS.

METHODS

Over a 129-month period (2 Jan 2002–30 Sep 2012), all patients undergoing ERCP at the University of Alabama at Birmingham were prospectively identified. At the time of the procedure, data on patient demographics, diagnostic work-up and therapeutic interventions were entered into an IRB approved database (#X030409001). During this study period, our practice has been to routinely place a single 7 or 10 Fr plastic (Cook Inc., Winston Salem, NC, USA) or metal stent. During this time, three experienced therapeutic endoscopists placed these stents. In general, SEMS were placed in patients with locally advanced malignant disease with good functional status. We prefer placement of 10-Fr biliary plastic stents in all patients except children and those with small bile leaks. Sphincterotomy was done using an ERBE generator (ERBE USA, Moulton, GA, USA) using the Endocut feature. All complications were assessed prospectively with follow up at 24–48 h and 1 month by an experienced nurse to check for complications that were recorded using consensus criteria.⁶

Statistical analysis

Continuous variables such as age were reported in terms of their mean and range, and *t*-test was done to test their mean difference. Contingency table analysis was carried out to compare the rates of pancreatitis, cholangitis, bleeding, and perforation in patients undergoing bile duct stent placement with and without sphincterotomy, and also for comparing pancreatitis rates across the types, caliber and length of stent. Fisher's exact test and chi-squared test were used for these comparisons with the type I error rate fixed at 5%. SAS software, version 9.3 (SAS institute, Cary, NC, USA) was used to conduct data analysis.

RESULTS

Figure 1 illustrates the process of patient selection. Over the 129-month study period (from January 2002 to September 2012), 7181 ERCP were done on 5020 patients. Among them, 3352 patients who did not undergo biliary stent placement were excluded from this analysis

and 426 patients who had previously undergone precut sphincterotomy, biliary sphincterotomy or pancreatic sphincterotomy or who had undergone additional endoscopic therapy (precut sphincterotomy, pancreatic sphincterotomy or stone extraction) were also excluded. The study thus included 1112 patients who underwent ERCP and biliary stent placement without EBS and 130 patients who underwent ERCP with EBS (Table 1). Of these 1242 patients, 911 (73.3%) underwent ERCP for the first time, 135 (10.9%) underwent the procedure for stent exchange, and 196 (15.8%) underwent additional endoscopic treatment (brushing, biopsy, and balloon dilation). No difference in repeat ERCP was found between the two groups (26% without EBS vs 30% with EBS; $P = 0.36$).

Table 2 provides the characteristics of complications and the overall ERCP complication rate during the period of study, which was 2.6%. There was no difference in complication rate based upon stenting without sphincterotomy or stenting with sphincterotomy (2.5% without EBS vs 3.1% with EBS, $P = 0.0719$). Of the patients with pancreatitis, it was found to be mild in 17 and moderate in eight patients and there was no difference between the two groups of patients in terms of severity of pancreatitis ($P > 0.9999$). Patients with pancreatic cancer were less likely to develop pancreatitis than those without pancreatic cancer ($3/424 = 0.71\%$ vs $22/818 = 2.69\%$, $P = 0.0182$).

None of the 1112 patients undergoing stenting without sphincterotomy had bleeding and one patient undergoing stenting with sphincterotomy had bleeding that was mild and self-limited.

The size and caliber of deployed stents are listed in Table 3. There was no difference in pancreatitis rate based on type of stent (2.3% plastic vs 0.5% metal, $P = 0.1465$) and caliber and length of stent (2.5% 10 Fr vs 1% <10 Fr, $P = 0.2793$; 2.7% for 10 cm long vs 1.9% for <10 cm long, $P = 0.4852$). All but four metallic stents were uncovered.

In all patients, bile duct stents could be deployed; in four patients, when deploying a 10-Fr plastic stent, the endoprosthesis could not be advanced through the stricture as the stent was deployed too far from the ampulla; biliary access was again obtained and the 10-Fr stent was placed successfully. Over the entire study period in all 5020 patients, pancreatic duct stents were deployed in 683 patients, all of whom had prior or concurrent EBS. During follow up of the 1112 patients, stent migration was noted in four. Removal of a biliary stent was not needed in any patient who developed pancreatitis.

DISCUSSION

Although EBS is generally safe, the complications are well recognized and can be severe. In addition, EBS adds additional cost to the procedure of bile duct stent placement. In the present study, we demonstrated that single SEMS and plastic stents (7 and 10 Fr), can be deployed without prior EBS, regardless of indication.

Two prospective randomized studies have compared complications and outcomes for biliary stent placement with or without EBS.^{1,2} DiGiorgio and DeLuca² prospectively randomized 172 consecutive patients with inoperable malignant stricture to 10-Fr stent placement with or without EBS. The length of the stents was not specifically addressed. Stent insertion was

not statistically different between the two groups (95.8% with EBS vs 93.7% without). Bleeding was reported in three patients in those receiving prior EBS. Pancreatitis was noted in two patients from both groups. No difference was detected in migration rate. Artifon *et al.*¹ randomized 74 patients with malignant distal bile duct stricture who were receiving a self-expandable metallic stent (SEMS) to stent placement with or without EBS. As with the prior study, bleeding was only observed in those undergoing EBS. Stent migration was statistically higher in those receiving EBS. Pancreatitis was not reported. The stents were successfully deployed in all patients. Last, a retrospective study³ examined outcomes following SEMS for those with (27 patients) or without EBS (77 patients). As with the prior two studies, bleeding was only seen in those having EBS (5 vs 0). The success rate of stent placement was 100% in both groups.

There has been variable performance, as well as variable reporting, of the use of EBS prior to bile duct stent placement.^{7–17} For example, in recent studies evaluating metallic stent placement, two studies reported EBS in all patients^{12,17} whereas, in others, EBS was not mentioned.^{13,15} Similar results were reported in prior studies comparing different plastic stents.^{7–10,18}

The use of EBS prior to stent placement to decrease pancreatitis is controversial. Large series that have studied bile duct stent placement have found no relationship.¹⁹ Single or multicenter trials did not study bile duct stent placement alone as a risk factor for post-ERCP pancreatitis.^{20–24} Using multivariable analysis, bile duct stent placement, however, has been found to be associated with post-ERCP pancreatitis in some studies.²⁵ In a large single-center study of over 11 000 procedures, stent placement was not found to be associated with post-ERCP pancreatitis.²⁶ Prior studies using stents placed percutaneously seem to support a low rate of pancreatitis.^{27–30} The present study does not address whether there is a relationship between stent placement and post-ERCP pancreatitis, but it does also suggest lack of a relationship. However, the primary goal of our study was not to re-address the relationship between stent placement and post-ERCP pancreatitis as we had previously done,²⁵ rather to highlight that EBS is not necessary to place a bile duct stent.

The primary reason for avoiding EBS for the placement of a single stent, unless other indications for its performance are present, is a higher complication rate. Indeed, as noted above, in two randomized trials, one with plastic and one with covered SEMS, a higher complication rate was encountered if EBS was carried out.^{1,2} The main complication in these studies was bleeding and, while generally mild, bleeding can be severe and life-threatening. Migration of plastic stents seems to be higher with EBS³¹ with rates of up to 13% being reported.³² In this study,³² all patients had undergone EBS. The migration rate is also higher following EBS and placement of a covered metallic stent.¹ Such findings, however, have not been universal.³³ Some endoscopists may prefer to carry out a small sphincterotomy to secure access, but we feel this is generally unnecessary. Stenosis may occur following EBS;³⁴ whether placement of a stent would reduce that rate is unknown. Last, there is an incremental cost for carrying out EBS, which is substantial, factoring in the number of these procedures that are done yearly in the USA.

Our findings may not be generalizable to all centers. The stents were deployed by skilled endoscopists and this may be why our overall rate of pancreatitis was low. Also, our practice consists of patients who may require stent exchange, but it is important to note that even in these patients undergoing repeat stenting, EBS is not required. As noted above, our study can be considered a technical reminder and is not a definitive analysis of the relationship between stent placement and post-procedural pancreatitis. We have compared complication rates based upon use of EBS, recognizing the study was not randomized and the control group therefore not ideal.

In conclusion, the present study demonstrates that single bile duct stents, whether plastic or metal, can be deployed without the need for biliary sphincterotomy as recently recommended.³⁵ Performance of EBS prior to stent placement places the patient at risk, albeit small, for post-sphincterotomy bleeding as well as additional costs of the procedure and, perhaps, migration.

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Figure 1.
Flowchart of selection of patient group.

Table 1

Baseline characteristics of 1242 patients who had ERCP and biliary stent placement

	ERCP & biliary stent without EBS (N = 1112)	ERCP & biliary stent with EBS (N = 130)	P-value
Age (years) mean $\pm$ SD [range]	60.3 $\pm$ 15.3 [10–100]	59.2 $\pm$ 16.8 [17–92]	0.4228
Male, n (%)	645 (58.1%)	62 (47.7%)	0.0239
Race, n (%)			
Caucasian	853 (76.7%)	98 (75.4%)	0.5129
African-American	235 (21.1%)	31 (23.8%)	
Other	24 (2.2%)	1 (0.8%)	
Indication for stent, n (%) [†]			
Pancreatic cancer	411 (37%)	13 (10.0%)	<0.0001
Bile leak	153 (13.8%)	12 (9.2%)	0.1501
Cholangiocarcinoma	120 (10.8%)	14 (10.8%)	0.9939
Presumed malignant stricture	95 (8.5%)	17 (13.1%)	0.0877
Benign stricture	84 (7.6%)	17 (13.1%)	0.0293
Malignant obstruction	45 (4.1%)	5 (3.9%)	0.9123
Ampullary cancer	22 (2%)	3 (2.3%)	0.8003
PSC	17 (1.5%)	–	0.2436
Biliary dilation	7 (0.6%)	7 (5.4%)	<0.0001
Ampullary stenosis	1 (0.1%)	1 (0.8%)	0.1985

[†] Some patients had more than one indication.

EBS, endoscopic biliary sphincterotomy; ERCP, endoscopic retrograde cholangiopancreatography; PSC, primary sclerosing cholangitis.

Table 2

Complications in patients who had ERCP and biliary stent placement

	ERCP & biliary stent without EBS (N = 1112)	ERCP & biliary stent with EBS (N = 130)	P-value
Pancreatitis	23 (2.07%)	2 (1.54%)	>0.9999
Severity			>0.9999
Mild	15	2	
Moderate	8	0	
Stent type [†]			>0.9999
Metal	1	0	
Plastic	16	2	
Stent caliber [†]			>0.9999
<10 Fr	11	1	
10 Fr	8	1	
Stent length [†]			>0.9999
<10 cm	2	0	
10 cm	17	2	
Cholangitis	3 (0.27%)	0	>0.9999
Bleeding	0	1 (0.77%)	0.1039
Perforation	1 (0.09%)	0	>0.9999
Other	1 (0.09%)	1 (0.77%)	0.1972
Total no. complications	28 (2.5%)	4 (3.1%)	0.0719

[†] Stent information is missing.

EBS, endoscopic biliary sphincterotomy; ERCP, endoscopic retrograde cholangiopancreatography.

Table 3Stent characteristics[†]

	ERCP & biliary stent without EBS (N = 1112)	ERCP & biliary stent with EBS (N = 130)	P-value
Plastic	852 (76.6%)	111 (85.4%)	0.0002
Caliber			
<10 Fr	182 (21.4%)	21 (18.9%)	0.6519
10 Fr	670 (78.6%)	90 (81.1%)	
Length			
<10 cm	558 (65.5%)	78 (70.3%)	0.3064
10 cm	294 (34.5%)	33 (29.7%)	
Metal	190 (17.1%)	5 (3.8%)	

[†] Some patients had more than one stent with mixed type.

EBS, endoscopic biliary sphincterotomy; ERCP, endoscopic retrograde cholangiopancreatography.