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Cost Effectiveness and Clinical Efficacy of Biliary Stents in Patients Undergoing Neoadjuvant Therapy for Pancreatic Adenocarcinoma in a Randomized Controlled Trial

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Abstract

BACKGROUND AND AIMS—The optimal type of stent for the palliation of malignant biliary obstruction in patients with pancreatic adenocarcinoma undergoing neoadjuvant chemoradiotherapy with curative intent is not known. We performed a prospective trial comparing 3 types of biliary stents—fully covered self-expandable metal stents (fcSEMSs), uncovered self-expandable metal stents (uSEMSs), and plastic stents—to determine which best optimized cost effectiveness and important clinical outcomes.

METHODS—In this prospective, randomized trial, consecutive patients with malignant biliary obstruction from newly diagnosed pancreatic adenocarcinoma who were to start neoadjuvant chemoradiotherapy were randomized to receive fcSEMSs, uSEMSs, or plastic stents during index ERCP. The primary outcomes were time to stent occlusion, attempted surgical resection, or death

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after the initiation of neoadjuvant therapy and the secondary outcomes were total patient costs associated with the stent, including the index ERCP cost, downstream hospitalization cost due to stent occlusion, and the cost associated with procedural adverse event.

RESULTS—A total of 54 patients were randomized and reached the primary endpoint; 16 patients in the fcSEMS group, 17 in the uSEMS group, and 21 in the plastic group. No baseline demographic or tumor characteristic differences were noted between groups. fcSEMSs had a longer time to stent occlusion compared with uSEMSs and plastic stents (219 vs. 88 and 75 days, $p<0.01$), although the groups had equivalent rates of stent occlusion, attempted surgical resection, and death. Although SEMs placement cost more during index ERCP (uSEMS = \$24,874 and fcSEMS = \$22,729 vs plastic = \$18,701, $p<0.01$), they resulted in higher procedural adverse event costs per patient (uSEMS \$5521 and fcSEMS=\$12,701 vs plastic = \$0, $p<0.01$). Conversely, plastic stents resulted in a \$11,458 hospitalization cost per patient due to stent occlusion, compared with \$2301 for uSEMSs and \$0 for fcSEMSs ($p<0.01$). The total cost of the index ERCP, procedural adverse events associated with the index ERCP and adverse events from stent occlusion were similar between stent types (fcSEMSs = \$41,112; uSEMSs = \$41,475; and plastic = \$39,955; $p=1.00$). There was no difference between groups in terms of number of days hospitalized for index ERCP adverse event and/or stent occlusion, although fcSEMSs resulted in fewer total days (3) of neoadjuvant treatment delay than uSEMSs (39) or plastic stents (79) ($p<0.01$).

CONCLUSIONS—In a prospective trial comparing fcSEMSs, uSEMSs, and plastic stents for malignant biliary obstruction in patients undergoing neoadjuvant therapy with curative intent for pancreatic adenocarcinoma, no stent type was superior in optimizing cost effectiveness, although fcSEMS resulted in fewer days of neoadjuvant treatment delay and a longer time to stent occlusion. (ClinicalTrials.gov, number NCT01038713)

Keywords

ERCP; pancreatic adenocarcinoma; stent; neoadjuvant; SEMs; plastic

INTRODUCTION AND BACKGROUND

Extrahepatic malignant biliary obstruction due to pancreatic adenocarcinoma requires palliation if the patient is not deemed to be a candidate for upfront surgical resection.^{1,2} In addition, patients who undergo neoadjuvant therapy with planned surgical curative intent must be palliated for the 5 to 6 months before resection.³ For these patients, treatment consists of placing a temporary plastic or self-expandable metal stent (SEMS) to relieve clinical symptoms and allow for normalization of liver tests so that neoadjuvant therapy can be given.⁴

Although SEMs appear to be the optimal stent type for patients deemed to be unresectable given their better patency rates, the optimal stent type in patients undergoing neoadjuvant therapy is controversial.^{5,6} Along with their better patency rates, SEMs have a higher periprocedural adverse event rate and cost more than plastic stents.⁷ Thus, although SEMs have better patency rates than plastic stents, their effectiveness may be offset by associated increases in “downstream” health-related and economic costs. In the specific population of

patients with malignant biliary obstruction undergoing neoadjuvant therapy with curative intent, plastic stents may actually be more advantageous due to less overall cost and adverse events such as treatment delay.

We performed a prospective, comparative effectiveness trial evaluating 3 types of biliary stents—fully covered self-expandable metal stents (fcSEMSs), uncovered self-expandable metal stents (uSEMSs), and plastic stents—to determine which best optimized cost effectiveness and important clinical outcomes in patients undergoing neoadjuvant therapy. A priori, we predicted that plastic stents would be as cost effective as SEMSs in regard to total patient costs associated with the stent, including the index endoscopic retrograde cholangiopancreatography (ERCP) cost, downstream hospitalization cost due to stent occlusion and the cost associated with procedural adverse events.

METHODS

Study Design

We enrolled patients at a single, tertiary care, academic medical center in the United States from February 2010 to April 2013 after approval from the Committee for the Protection of Human Subjects (CPHS #22104) on December 9, 2009. Additional study monitoring was performed by the Norris Cotton Cancer Center (Dartmouth) Data Safety Monitoring and Accrual Committee. The study was registered at ClinicalTrials.gov (number NCT01038713) and reported under the auspices of the CONSORT guidelines.⁸

Patients

All patients were adults able to provide written, informed consent. Patients were included if they were referred for endoscopic retrograde cholangiopancreatography (+/- endoscopic ultrasound [EUS]) at Dartmouth-Hitchcock Medical Center for palliation of extrahepatic malignant biliary obstruction due to pancreatic adenocarcinoma. At the time of enrollment, all patients had cross-sectional imaging suggestive of resectable, borderline or locally unresectable invasive pancreatic ductal adenocarcinoma before their ERCP as defined by the American Hepato-Pancreatico-Biliary Association convened consensus conference on pancreatic cancer.⁹ Patients were required to have clinical, radiographic and cross-sectional imaging findings consistent with extrahepatic biliary obstruction requiring stent placement. If at the time of ERCP and/or EUS patients were deemed to have disease that would not potentially benefit from neoadjuvant therapy by being downstaged to resectable disease, they were excluded from the study. All participants must have had planned follow-up at our institution; patients with planned neoadjuvant therapy at another institution were excluded. Patients in whom stent placement could not be performed were not included in the study. All patients had verified pancreatic adenocarcinoma via fine-needle aspiration or exploratory laparoscopy.

Randomization

Randomization was conducted during the ERCP after biliary access had been obtained with an access wire based on a web-based random number generator. All patients who had wire

access achieved were subsequently able to have a stent placed. Neither the endoscopist nor patient was blinded to the randomization assignment.

Intervention

Procedures were performed by one of 2 experienced therapeutic endoscopists under conscious or monitored anesthesia. After successful bile duct cannulation and wire placement, patients were randomized to receive a fully-covered self-expandable metal (fcSEMS), uncovered self-expandable metal (uSEMS), or plastic stent. Both SEMS were 10 mm Wallflex stents of varying lengths (6,8,10 cm) (Boston Scientific, Marlborough, Mass) and plastic stents were 10 French Cotton-Leung stents (7, 9, 12 cm) (Cook Endoscopy, Winston-Salem, NC). The length of stent was chosen at the discretion of the treating endoscopist. All procedure-related maneuvers and interventions were managed by the attending endoscopist. Multiple stents were not placed in any of the patients. Routine overnight observation of patients after ERCP was not performed.

Neoadjuvant Therapy

After stent placement, patients were referred to the Dartmouth multidisciplinary pancreas tumor clinic where a neoadjuvant treatment protocol was initiated. All patients underwent neoadjuvant chemoradiotherapy using one of 3 chemoradiotherapy regimens. Patients eligible for an ongoing clinical trial received cetuximab 400 mg/m² IV once followed by 250 mg/m² IV weekly and gemcitabine biweekly 50 mg/m² IV over 6 weeks with concurrent radiotherapy 5400 cGy over 28 fractions (Regimen 1). Other patients received one of 2 preoperative regimens based on previous Dartmouth protocols. One regimen consisted of docetaxel 65 mg/m² IV and gemcitabine 4000 mg/m² IV given on days 1, 15, and 29, followed on day 43 by radiotherapy at 50.4 Gy with gemcitabine 50 mg/m² IV twice weekly for 12 doses (Regimen 2). The other regimen consisted of radiotherapy of 50.4 Gy in 28 fractions, concurrent with gemcitabine 50 mg/m² biweekly for 6 weeks (Regimen 3).¹⁰⁻¹² The regimen which each patient received was not randomized at the time of stent placement and was instead determined by the subsequent treating oncologist. At the completion of neoadjuvant chemoradiotherapy, all patients underwent attempted operative pancreatic resection unless restaging cross-sectional imaging or diagnostic laparoscopy demonstrated evidence of unresectability.

Outcome Measurements

The primary outcome was time to stent occlusion, attempted surgical resection, or death after the initiation of neoadjuvant therapy. Stent occlusion was defined as a rise in total bilirubin and/or concomitant cholangitis associated with the need for stent replacement via ERCP at the discretion of the clinical treatment team. Once patients had occluded their stent, participation in the study was finalized after documentation of the number of hospital days the patient was hospitalized to address the stent occlusion and/or the number of days of neoadjuvant treatment delay. In patients whose primary outcome was attempt at surgery or death, the study was completed when those events occurred. The first secondary outcome was the total cost of the index ERCP, including the stent cost, endoscopist professional fee, hospital technical fee, and anesthesia fee. The second secondary outcome was the cost of any associated adverse event of the ERCP, including the cost of subsequent hospitalization.

The third secondary outcome was the cost of stent occlusion, including any hospitalization costs, as well as the number of hospitalization days and the number of days neoadjuvant therapy was delayed. All cost data were derived from the actual hospital charges for each patient obtained from billing records from Dartmouth-Hitchcock Medical Center. Billing costs were not adjusted to 2016 dollar values.

Statistical Analysis

Descriptive statistics were used to characterize the population and are reported as means, standard deviations, and 95% confidence intervals. The Fisher exact test was used to compare categorical variables and ANOVA was used to compare continuous variables. Analysis was via treated patients; ie, only those patients who reached the primary outcome were included in the analysis. A normal distribution was not calculated for each group. An alpha level of 0.05% was set for statistical significance. All statistical analysis was performed using Microsoft EXCEL (Microsoft Corporation, Redmond, Wash) and Graphpad (Graphpad Software, Inc., San Diego, Calif).

RESULTS

Patients

From February 2010 to April 2013, all patients referred for ERCP at our institution for malignant biliary obstruction due to presumed pancreatic adenocarcinoma were screened for eligibility and offered inclusion into the study if eligible. 63 patients were eventually enrolled in the study and 54 completed the study and reached the primary outcome (Figure 1) after initiating neoadjuvant therapy with curative intent. One patient, a 75-year-old male, died 8 days after his index ERCP from PEP after his family pursued comfort measures only care in a tumor that was locally unresectable and was excluded from final analysis. 6 patients received regimen 1, 12 received regimen 2 and 36 received regimen 3. 94% of the plastic stents placed were 7 cm in length; only one stent was 12 cm in length.

All patients reached 1 of the 3 primary clinical outcomes by December 2014. Baseline patient characteristics were similar between groups in terms of age, gender, tumor size, and resectability status (Table 1).

Study Outcomes

The primary study outcomes are shown in Table 2. The groups had equivalent rates of stent occlusion, attempted surgical resection and death, although fcSEMS had a longer time to stent occlusion compared with uSEMSs and plastic (219 vs 88 and 75 days, $p<0.01$). Although it was not statistically significant, there was trend toward more procedural adverse events during the index ERCP in patients who were randomized to receive SEMS. All patients with stent occlusion underwent a repeat ERCP.

The secondary cost and clinical outcome data are displayed in Table 3. SEMS placement cost more during index ERCP (uSEMS = \$24,874 and FcSEMS = \$22,729 vs. plastic = \$18,701, $p<0.01$), and they also resulted in higher procedural adverse event costs per patient (uSEMS \$5521 and fcSEMS=\$12,701 vs plastic = \$0, $p<0.01$). Conversely, plastic stents

resulted in a \$11,458 hospitalization cost per patient due to stent occlusion, compared with \$2,301 for uSEMSs and \$0 for fcSEMSs ($p < 0.01$). The total cost of the index ERCP, procedural adverse events associated with the index ERCP, and adverse events from stent occlusion were similar between stent types (fcSEMS = \$41,112; uSEMS = \$41,475; and plastic = \$39,955; $p = 1.00$) (Fig. 2).

Although fcSEMSs resulted in no hospitalizations due to stent occlusion and only limited neoadjuvant treatment delay, 15 days were spent in the hospital for adverse events related to the index ERCP. Conversely, plastic stent placement resulted in 79 days total days of delay in neoadjuvant therapy, but resulted in no hospital days due to index ERCP procedural adverse events (Fig. 3).

DISCUSSION

Our findings demonstrate that in a prospective trial comparing fcSEMSs, uSEMSs, and plastic stents for malignant biliary obstruction in patients undergoing neoadjuvant therapy with curative intent for pancreatic adenocarcinoma, no stent type was superior in optimizing cost effectiveness, although fcSEMSs resulted in fewer days of neoadjuvant treatment delay. These findings therefore support the use of fcSEMSs as a cost-effective, first-line stent choice in the neoadjuvant patient population.

Palliation of malignant biliary obstruction due to pancreatic adenocarcinoma has transitioned over the past 3 decades from a surgical/percutaneous approach to an endoscopic one because endoscopic stent placement is more comfortable and less invasive to patients.^{7,13,14} In those patients who are not eventual candidates for surgical resection, SEMSs are clearly superior to plastic stents because they are less likely to occlude and likely are more cost effective.^{5,7}

However, in patients undergoing neoadjuvant therapy who require 5 to 6 months of stent patency between index ERCP and surgical resection, the optimal stent type is controversial. Although plastic stents are more likely to occlude, they are less likely to be associated with upfront procedural adverse events such as PEP or perforation. Therefore it is unclear if the patency benefit of SEMS is offset by their more frequent upfront adverse event rate in terms of overall cost and clinical outcomes.

Our center is uniquely poised to conduct this trial because it is one of the few academic centers which exclusively treats resectable, borderline, and locally unresectable pancreatic adenocarcinoma using a neoadjuvant approach. In addition, due to our rural location in northern New England, there are no competing centers in our catchment region which could undermine patient follow-up. We deliberately chose not to perform a multicenter trial because of a desire to limit the confounding associated with using the billing practices of multiple payers and health systems.

We examined cost as an outcome given the current emphasis on cost containment in the United States healthcare system. Not only was it important to evaluate the upfront costs of the ERCP, including the cost of the stent, it was critical to see if the long-term costs associated with stent dysfunction could be quantified. We also chose to include the total

days of hospitalization from adverse events associated with the index ERCP, as well as those due to stent occlusion, as important clinical outcomes. Finally, because it is critical to avoid treatment delay during neoadjuvant therapy, the number of days that neoadjuvant was delayed due to a stent-related adverse event was also determined.

The most striking finding was that when all of the upfront and downstream costs were considered, fcSEMSs, uSEMSs, and plastic stents had equivalent cost effectiveness. In addition, the total number of hospital days associated with procedural and/or stent occlusion were similar between groups. However, in terms of minimizing the delay in neoadjuvant therapy, fcSEMSs were clearly superior because their risk of occlusion was the lowest of the 3 stent types. For this reason, we believe fcSEMSs should be the stent of choice used in this patient population.

Interestingly, all of the PEP cases in the fcSEMS group and one in the uSEMS group occurred during the first 6 months of the study when sphincterotomy was not being routinely performed during placement of SEMs. After the third episode of PEP, sphincterotomies were routinely performed in all patients receiving SEMs, and only 2 further episodes of PEP occurred.¹⁵ This suggests a learning curve which, had the study been started after the initiation of routine sphincterotomy, potentially would have resulted in an even more robust clinical benefit to SEMs.

How can this study be used clinically? Based on these findings, it may be prudent to switch practice to exclusively using fcSEMS for the palliation of malignant biliary obstruction in patients undergoing neoadjuvant therapy with curative surgical intent. All patients should probably receive a sphincterotomy before stent placement, which likely decreases the rate of PEP. The silastic polymer coating over the fcSEMS also makes it easier for the surgical oncologist to remove the stent at the time of operative resection.³

There are weaknesses to the study, most notably its sample size. However, randomization revealed no differences in the baseline patient characteristics between groups and the 2 economic and/or clinical outcome differences found in the study (increased time to stent occlusion and less days of neoadjuvant treatment delay in the fcSEMS patients) would likely remain significant even with a larger study. We deliberately did not perform a multicenter trial due to the inherent difficulties in evaluating multiple billing systems. The study also did not adjust for 2016 dollars, which likely caused the total costs to be lower than would be expected if the study were performed today and also relied completely on billable data from our institution that was not prospectively collected at the time of each event. In addition, stent occlusion was at the discretion of the treating endoscopist so that selection bias may have been introduced into the primary outcome measurement. However, we aimed to mirror the clinical setting in which stent occlusion is determined based on clinical judgment, ie, biochemical derangement and/or cholangitis. Furthermore, the study lost 3 patients to follow-up, and an analysis of only those patients who reached the primary outcome was performed; an intention-to-treat analysis was not performed. Finally, although it is not statistically significant, two-thirds of plastic and uSEMS patients had locally advanced disease compared with one-third in the fcSEMS group which might have influenced stent patency.

In conclusion, we found in a prospective trial comparing fcSEMSs, uSEMSs, and plastic stents for malignant biliary obstruction in patients undergoing neoadjuvant therapy with curative intent for pancreatic adenocarcinoma, that no stent type was superior in optimizing total cost effectiveness, although fcSEMSs resulted in fewer days of neoadjuvant treatment delay.

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Abbreviations

EUS	Endoscopic Ultrasound
ERCP	Endoscopic Retrograde Cholangiopancreatography
fcSEMS	fully-covered self-expandable metal stent
PEP	post-ERCP pancreatitis
uSEMS	uncovered self-expandable metal stent
US	United States

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Figure 1.
Enrollment and outcomes

Figure 2.

Total procedural, adverse event, and hospitalization costs per stent type. *This number includes the total cost of the index ERCP, cost associated with procedural adverse events from the index ERCP and hospitalization costs associated with stent occlusion.

Figure 3.
Inpatient hospitalization days based on stent type

Table 1

Baseline Patient Characteristics

Characteristic	fcSEMS (n=16)	uSEMS (n=17)	Plastic (n=21)	P value
Age – yr.	67.2	64.8	65.9	0.27
Female Sex – no. (%)	7 (43)	6 (35)	10 (48)	0.34
Tumor Size – mm	30.1	37.0	34.2	0.27
Resectability Status – no. (%)				
Resectable	5 (31)	2 (12)	3 (14)	0.30
Borderline	6 (38)	4 (25)	4 (19)	0.43
Locally Advanced	5 (31)	11 (65)	14 (67)	0.07
Procedural adverse event requiring hospitalization – no. (%)	4 (25)	3 (18)	0 (0)	0.06
Monitored Anesthesia Care – no, (%)	9 (56)	14 (82)	14 (66)	0.27

Table 2

Primary Clinical Outcomes

Characteristic	fcSEMS (n=16)	uSEMS (n=17)	Plastic (n =21)	P value
Stent Occlusion – no. (%)	4 (25)	6 (35)	11 (52)	0.22
Mean Days until Endpoint (range)	219 (21-341)	88 (45-171)	75 (7-161)	<0.01
Attempted Surgical Resection – no. (%)	8 (50)	6 (35)	4 (19)	0.14
Mean Days until Endpoint (range)	165 (127-193)	165 (133-193)	150 (101-184)	0.63
Death – no. (%)	4 (25)	5 (29)	6 (29)	0.96
Mean Days until Endpoint (range)	71 (7-196)	241 (122-453)	187 (96-312)	0.11

Table 3

Secondary Clinical Outcomes

Characteristic	fcSEMS (n=16)	uSEMS (n=17)	Plastic (n=21)	P value
Index ERCP Cost *				
Total Cost/Patient	\$22,729	\$24,874	\$18,701	<0.01
Stent Cost/Patient	\$4,274	\$3,446	\$116	<0.01
Professional Fee Cost/Patient	\$3,836	\$5,217	\$5,069	0.32
Technical Fee Cost/Patient	\$6,615	\$8,819	\$7,658	0.17
Anesthesia Fee Cost/Patient	\$5,022	\$5,282	\$4,066	0.28
Procedural adverse event				
Adverse event cost/patient	\$12,701	\$5,521	\$0.00	<0.01
<i>Post-ERCP Pancreatitis – no. (%)</i>	3 (19)	3 (18)	0 (0)	0.12
<i>Adverse event cost/patient</i>	\$4,053	\$5,021	0.00	<0.01
<i>Hospitalization Days (range)</i>	15 (0-8)	14 (0-6)	0 (0-0)	<0.01
Stent Occlusion				
Hospitalization Cost/Patient	\$0	\$2,301	\$11,458	<0.01
Hospitalization Days (range)	0 (0-0)	5 (0-3)	32 (0-8)	<0.01
Days Neoadjuvant Therapy Delayed	3 (0-3)	39 (7-17)	79 (0-17)	<0.01
Estimated Repeat ERCP Cost/Patient [†]	\$5,682	\$8,779	\$9,796	0.39

* Costs represent the actual amount in United States dollars billed to the patient or secondary payer by the treating medical center

[†] Estimate derived by dividing the index ERCP cost/number of patients requiring ERCP to treat stent occlusion