

Expandable Metal Biliary Stents Before Pancreaticoduodenectomy for Pancreatic Cancer: A Monte-Carlo Decision Analysis

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Background & Aims: Endoscopic placement of plastic or self-expandable metal biliary stents (SEMS) relieves obstructive jaundice from pancreatic cancer. Short-length, distally placed SEMS do not preclude subsequent pancreaticoduodenectomy. We sought to determine whether SEMS placement in patients whose surgical status is uncertain is cost-effective for management of obstructive jaundice. **Methods:** A Markov model was constructed to evaluate costs and outcomes associated with endoscopic biliary stenting for obstructive jaundice. Strategies evaluated were: (1) initial plastic stent with plastic stents for subsequent occlusions in nonsurgical candidates after staging (plastic followed-up by [f/u] plastic), (2) initial plastic with subsequent SEMS (plastic f/u metal), (3) initial short-length SEMS with subsequent plastic (metal f/u plastic), and (4) initial short-length SEMS with subsequent expandable metal stent (metal f/u metal). Published stent occlusion rates, ERCP complication rates and outcomes, cholangitis rates and outcomes, pancreatic cancer mortality rates, and Whipple complication rates were used. Costs were based on 2004 Medicare standard allowable charges and were accrued until all patients reached an absorbing health state (death or pancreaticoduodenectomy) or 24 cycles (24 mo) ended. **Results:** Average costs per patient from Monte Carlo simulation were: (1) metal f/u metal, \$19,935; (2) plastic f/u metal, \$20,157; (3) metal f/u plastic, \$20,871; and (4) plastic f/u plastic, \$20,878. For initial plastic stents to be preferred over short-length metal stents, 70% or more of pancreatic cancers would need to be potentially resectable by pancreaticoduodenectomy. **Conclusions:** In patients undergoing ERCP before definitive cancer staging, short-length SEMS is the preferred initial cost-minimizing strategy.

Pancreatic cancer is highly lethal and is the second most frequent gastrointestinal malignancy with approximately 29,000 new cases diagnosed in the United States annually.¹ Eighty-five percent to 90% of pancreatic cancers are adenocarcinomas arising from ductal cells and are associated with a 5-year survival rate of less than 5% and an overall median survival of 4 to 6 months.²

Obstructive jaundice develops in 70%–90% of patients with pancreatic carcinoma and may result in intractable pruritus, progressive hepatocellular dysfunction, coagulopathy, and malabsorption.^{3,4}

Palliative relief of malignant biliary obstruction may be accomplished via surgical, radiologic, or endoscopic techniques. Although these treatment modalities are equally effective in biliary decompression, surgical and radiological decompression are associated with substantially higher morbidity and mortality than endoscopically placed endoprostheses.^{5–7} Thus, endoscopic placements of biliary stents via endoscopic retrograde cholangiopancreatography (ERCP) are preferred when feasible.

Since the introduction of polyethylene (plastic) stents in the late 1970s, they have been used widely because of their ease of insertion and low costs. However, plastic stents occlude as a result of bacterial biofilm formation and biliary sludge.⁸ Self-expandable metal stents (SEMS) were developed with the goal of achieving prolonged stent patency, but they are more expensive than plastic stents. Of note, patients with pancreatic cancer commonly present with jaundice and may undergo ERCP before definitive cancer staging or assessment of surgical candidacy. During this initial ERCP, biliary stenting almost always is performed using plastic stents for several reasons. It generally is perceived that, first, metal stents will preclude subsequent Whipple resection; second, that the potential benefit and more durable patency of metal stents will not be realized, and, third, that the additional cost of the metal stent will not be justified. A fourth important consideration is that long-length metal stents may preclude a patient with localized disease from un-

Abbreviations used in this paper: ERCP, endoscopic retrograde cholangiopancreatography; f/u, followed-up by; QALY, quality-adjusted life year; SEMS, self-expandable metal stents.

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1542-3565/05/\$30.00

PII: 10.1053/S1542-3565(05)00886-4

dergoing a successful pancreaticoduodenectomy (Whipple procedure) because there may be an inadequate length of residual bile duct for creation of the choledochojejunal anastomosis.⁹ An alternative to the long-length metal stent is to use short-length (40 mm) expandable metal stents that traverse the malignant stricture but do not prevent subsequent Whipple resection because they leave adequate bile duct for anastomosis and are removed en bloc with the cancer.⁹ If the patient is determined to be unresectable either at the time of surgery, or is a poor surgical candidate for a Whipple resection, the initial short-length metal stent can remain in situ and provide more durable patency than plastic stents, albeit at a higher initial cost than plastic stents. The subsequent choice of stent then will depend on the endoscopist's preferences, experience, and the patient's life expectancy.

Based on these considerations, endoscopists use either metal or plastic stents for the relief of malignant obstructive jaundice from pancreatic cancer. In the current medical environment, costs weigh heavily on clinical decision making. However, there is a paucity of cost-analysis studies comparing metal vs plastic stents for the management of malignant obstructive jaundice. Specifically, there are no cost-analysis studies examining the use of short-length metal stents before possible pancreaticoduodenectomy for pancreatic cancer. We analyzed costs, occlusion rates, complications, and cholangitis rates of preoperative placement of short-length metal stents vs plastic stents to better define their role in the management of obstructive jaundice from pancreatic cancer. Our analysis assessed how surgical status and potential Whipple surgery affect expected costs.

Methods

Overview of Analysis

Markov models were constructed using Excel XP spreadsheets (Microsoft Corp., Redmond, WA) with supplemental software (XLSim; AnalyCorp, Palo Alto, CA) to evaluate the expected costs and outcomes associated with biliary stenting via ERCP in a hypothetical cohort of patients presenting with obstructive jaundice from pancreatic cancer. Patients were potential surgical candidates for the Whipple procedure depending on the stage of their disease. The strategies evaluated were as follows: (1) initial plastic stent followed-up by repeat plastic stents for subsequent occlusions (plastic f/u plastic), (2) initial plastic stent followed-up by metal stents for subsequent occlusions (plastic f/u metal), (3) initial metal stent followed-up by plastic stents for subsequent occlusions (metal f/u plastic), and (4) initial metal stent followed-up by metal stent for subsequent occlusions (metal f/u metal).

Decision analysis uses data available in the medical literature to produce a model of possible outcomes associated with

a particular disease to facilitate the determination of the most desirable health care strategy among different alternatives. A theoretic cohort of patients with the disease of interest is modeled with transition probabilities leading to distinct health states (Markov states) that each are associated with particular outcomes over a defined time period (Markov cycles). Costs and health outcome consequences are attached to each Markov state with defined transitional probabilities. The decision-analysis model is run over various cycles to simulate the natural history of the disease of interest, accruing associated costs and outcomes expected from different competing health care strategies.¹⁰

Stent occlusion rates, ERCP complication rates and outcomes, cholangitis rates and outcomes with stent occlusions, and pancreatic cancer mortality rates used in the model were derived from the medical literature, as described later. These values were converted to probabilities with which our theoretic cohort moved from one health state to another. The cycles of our model were 1 month in duration. The costs and health outcomes were accrued until all the patients had reached an absorbing health state (death or Whipple surgery) or a total of 24 cycles (2 y) was reached. Discounting for health outcomes and costs was not performed because of the short survival of this patient cohort.

Ovid Medline (dates of search from 1996 to week 4 of 2004) was cross-searched with the following key words: endoscopic retrograde cholangiopancreatography or ERCP, and biliary obstruction or endoprotheses or obstructive jaundice or occlusion or stent, and cancer or carcinoma or malignant or pancreatic neoplasms. The search identified 185 articles. After exclusion of articles including the following key words: ampulla of Vater or autoimmune disease or cholangiocarcinoma or cholelithiasis or cystadenoma or gallbladder or gallstones or hepatocellular carcinoma or pancreatitis or sclerosing cholangitis, 97 articles remained. Of these, 85 articles remained after limiting the articles to human studies and publication in English. These articles were reviewed for clinical relevance to our decision analysis, and 11 articles remained after eliminating articles on nonrelated topics. Fifteen additional articles were identified by review of article references, for a total of 26 articles.^{3-7,11-31} The studies included then were weighted by sample size (n) to determine average probabilities and transition values in a pooled analysis, which is summarized in Table 1.

Model of Obstructive Jaundice From Pancreatic Carcinoma

The main questions of interest addressed by this Markov decision-analysis model were as follows:

1. When a patient with obstructive jaundice from pancreatic cancer presents to an endoscopist before cancer staging, what type of stent (metal vs plastic) initially provides the preferred cost-minimizing strategy? Should a short-length metal stent or a plastic stent be

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