

Plastic biliary stent patency in patients with locally advanced pancreatic adenocarcinoma receiving downstaging chemotherapy

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Background: Plastic stents in patients with biliary obstruction caused by pancreatic adenocarcinoma are typically exchanged at 3-month intervals. Plastic stents may have reduced durability in patients receiving chemotherapy.

Objective: To determine the duration of plastic biliary stent patency in patients undergoing chemotherapy for pancreatic adenocarcinoma.

Design: Retrospective, multicenter cohort study.

Setting: Three tertiary academic referral centers.

Patients: A total of 173 patients receiving downstaging chemotherapy for locally advanced or borderline resectable pancreatic adenocarcinoma from 1996 to 2013.

Interventions: Placement of 10F or larger plastic biliary stents.

Main Outcome Measurements: Primary outcome was overall duration of stent patency. Secondary outcomes included the incidence of premature stent exchange (because of cholangitis or jaundice) and hospitalization rates.

Results: A total of 233 plastic stents were placed, and the overall median duration of stent patency was 53 days (interquartile range [IQR] 25–99 days). Eighty-seven stents were removed at the time of surgical resection, and 63 stents were exchanged routinely per protocol. The remaining 83 stent exchanges were performed for worsening liver function test results, jaundice, or cholangitis, representing a 35.6% rate of premature stent exchange. The median stent patency duration in the premature stent exchange group was 49 days (IQR 25–91 days) with a 44.6% hospitalization rate. The overall rate of cholangitis was 15.0% of stent exchanges, occurring a median of 56 days after stent placement (IQR 26–89 days).

Limitations: Retrospective study.

Conclusions: Plastic biliary stents placed during chemotherapy/chemoradiation for pancreatic adenocarcinoma have a shorter-than-expected patency duration, and a substantial number of patients will require premature stent exchange. Consideration should be given to shortening the interval for plastic biliary stent exchange. (*Gastrointest Endosc* 2015;81:360-6.)

(footnotes appear on last page of article)

Malignant biliary obstruction because of pancreatic adenocarcinoma can result in the development of jaundice and cholangitis. ERCP with biliary stenting by using either

a plastic stent or a self-expandable metal stent (SEMS) is commonly performed for relief of malignant biliary obstruction.¹⁻³

Several factors can influence the choice of stent placement in malignant biliary obstruction. Plastic stents are relatively inexpensive compared with metal stents; the latter can be 15 to 40 times more expensive.^{4,5} However, plastic stents are associated with a shorter median patency duration of 3 to 4 months compared with 9 months for SEMSs.^{5,6} Occlusion of plastic stents tends to occur from biofilm formation on the inner stent surface as a result



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of bacterial colonization and from bilioduodenal reflux.⁷⁻⁹ Various cost analyses have suggested that the use of plastic stents is only favorable in patients who are expected to survive less than 4 to 6 months.^{4,6,10-12}

A recent study suggested that plastic stents may have reduced durability in patients receiving chemotherapy for pancreatic adenocarcinoma.⁵ We sought to further investigate this issue by examining the patency rates and adverse events associated with plastic biliary stent placement in patients with locally advanced or borderline resectable pancreatic adenocarcinoma undergoing chemotherapy/chemoradiation.

PATIENTS AND METHODS

Participating centers

We performed a retrospective study at 3 tertiary care centers: Ronald Reagan UCLA Medical Center (Los Angeles, Calif), Northwestern Memorial Hospital (Chicago, Ill), and the Moffitt Cancer Center (Tampa, Fla). Institutional review board approval was obtained for the research protocol at each institution.

Patients

Electronic medical records were retrospectively reviewed for all patients who underwent plastic biliary stent placement while receiving chemotherapy/chemoradiation for pancreatic cancer between April 1996 and February 2013.

Patients were included in the study if they had adenocarcinoma of the pancreas based on pathology or cytology and if they had locally advanced or borderline resectable disease based on staging by CT, magnetic resonance imaging, or EUS (Table 1). All patients included in the study had malignant biliary obstruction that was relieved by placement of a plastic biliary stent before undergoing chemotherapy/chemoradiation. Chemotherapy regimens were chosen at the discretion of the primary oncologist and predominantly included either a gemcitabine-based or 5-fluorouracil-based regimen. Patients were excluded from the study if they underwent immediate operative resection, presented initially with metastatic disease, had initial metal biliary stent placement, had initial/previous plastic biliary stent placement or any subsequent stent exchanges at another institution, or were lost to follow-up. Given that the causes of death were often unknown, patients were also excluded if they died before stent exchange.

Endoscopy and patient follow-up

For those patients meeting inclusion criteria, collected data included demographics, stent length and diameter, duration of stent patency, reason(s) for stent exchange or removal, total number of stent exchanges per patient, and hospitalization rates. Indications for stent

exchange/removal included planned stent exchange, premature stent exchange for abnormal liver function tests or cholangitis, or surgical resection. The type, length, and caliber of the plastic stents were chosen at the discretion of the endoscopist. All patients received a single plastic stent containing internal and external flaps. To eliminate a source of bias from small-diameter stents, which may contribute a disproportionately higher rate of stent occlusion, plastic stents measuring less than 10F in diameter were excluded from this study. Patients underwent routine staging CT scans during the time of treatment and when deemed by a multidisciplinary tumor board to be suitable for surgical exploration, underwent exploratory laparotomy with the intention of pancreaticoduodenectomy. Patients were followed until their tumors were resected, were deemed unresectable because of tumor progression despite treatment, underwent metal stent placement, or discontinued or completed chemotherapy.

Study outcomes and statistical analysis

The primary study outcome was the median overall duration of stent patency during treatment. Stent patency was defined as the time (in days) between stent placement and one of the following: planned stent exchange, stent occlusion requiring premature stent exchange (cholangitis or abnormal liver enzymes), or time of pancreaticoduodenectomy. Regarding patients who eventually received a metal biliary stent in their clinical course, analysis was limited to the period of time in which they had a plastic biliary stent. For the patients who ultimately died of their disease, analysis was terminated at their last stent exchange before death. Secondary outcomes included the incidence of premature stent exchange and the rates of hospitalization. Given that each patient may have had several procedures, each stent placed was recorded as an independent event, and all results are reported as per stent rather than per patient.

Descriptive statistics were used to characterize our population. Due to the non-normal distribution of stent patency, the median duration instead of the mean duration is reported for all figures. For the same reason, interquartile range (IQR) (ie, 25th-75th percentiles) is also reported. A 2-tailed Fisher exact test was used to compare categorical variables, with an alpha level of .05 set for statistical significance. Cumulative incidences of stent occlusion were examined with Kaplan-Meier analysis. Statistical analysis was performed by using GraphPad Prism (GraphPad Software, La Jolla, Calif).

RESULTS

A total of 434 patients underwent plastic stent placement during the study period, of whom 230 patients were excluded because of incomplete data, death after first stent

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