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Incidence of Hepaticojejunostomy Stricture Following Hepaticojejunostomy

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ABSTRACT

INTRODUCTION: Operations requiring biliary-enteric anastomosis are uncommon and the true incidence of postoperative stricture is unknown. Our goal was to determine the timing, incidence, and management of stricture after biliary-enteric anastomosis.

METHODS: We used 5% Medicare claims data (1996 to 2011) to identify patients ≥ 66 years who underwent an operation requiring a biliary-enteric anastomosis. A cumulative incidence curve was used to describe timing of stricture diagnosis. The use of imaging and intervention were evaluated. A Cox proportional hazards model was constructed to identify factors associated with stricture.

RESULTS: 3,374 patients underwent an operation requiring either a hepaticojejunostomy (54.33%; N=1,833) or choledochojejunostomy (45.67%; N=1,541); 2-year survival was 57.0%. Overall, 403 (11.9%) patients developed a stricture. The cumulative incidence of stricture was 12.5% at 2 years. Mean time to stricture diagnosis was 16.8 ± 21.6 months (median=8.5 months); 23% of patients with a stricture required hospitalization for cholangitis (N=94). Only 18 (4.5%) patients with a stricture required reoperation. Younger age (HR 0.98; 95% CI 0.98-0.99) was associated with decreased likelihood of stricture formation; presence of an endostent (HR 1.66; 95% CI 1.35-2.04) predicted stricture formation.

CONCLUSION: Biliary-enteric anastomotic strictures occur with significant frequency after a biliary-enteric anastomosis. Although many patients are managed non-operatively, stricture diagnosis remains burdensome.

INTRODUCTION

In patients with both benign and malignant disease, biliary reconstruction with biliary-enteric anastomosis is necessary in many cases. One of the long-term complications of biliary-enteric anastomosis (choledochojejunostomy or hepaticojejunostomy) is stricture, which can lead to multiple hospitalizations and procedures. Outside of liver transplant,¹⁻³ little is known about anastomotic stricture following biliary-enteric anastomoses, especially in benign disease. Based on small retrospective studies, the reported incidence in benign disease is 4-10%.⁴⁻⁶ In patients with pancreatic adenocarcinoma or cholangiocarcinoma, biliary obstruction and/or stricture is less common and, when it occurs, is thought to be secondary to recurrence of malignancy. Given the sparse reports on post-biliary-enteric anastomotic stricture, there is a need for more robust data to help surgeons assess and improve their own outcomes, and to understand the impact of a stricture on the patient's quality and duration of life.

Of the small subset of patients who are diagnosed with a biliary-enteric stricture, there are no current reports on assessment of resource utilization. Studies have reported various interventions including balloon dilation, stent placement, and reoperation. Studies have reported success rates in patients who undergo reoperation for biliary-enteric anastomosis either after pancreatic surgery or bile duct injury,^{7,8} however, endoscopic and percutaneous interventions are coming to the forefront.⁹⁻¹¹ While the need for repeat procedures with attendant morbidity may be expected, the incidence of these procedures remains unknown.

The purpose of this study was to examine the incidence of hepaticojejunostomy stricture after hepaticojejunostomy using a national claims database, determine the timing of stricture

formation, use of radiographic imaging and procedures, as well as incidence of reoperation in these patients.

METHODS

Data Source

This retrospective cohort study used enrollment and claims data for 5% Medicare beneficiaries from 1996 to 2011. Demographic and enrollment data were obtained from the Denominator file. The Medicare Provider Analysis and Review file (MEDPAR) was used to obtain inpatient hospital admission claims. Outpatient claims and claims submitted by non-institutional providers were obtained from the Outpatient Standard Analytic File (OUTSAF) and Carrier Standard Analytic File (SAF).

Cohort Identification

Cohort selection is summarized in Figure 1. Patients included in the cohort were identified based on International Classification of Diseases, 9th Edition (ICD-9) procedure and Current Procedural Terminology codes (CPT) (Table 1). Patients were included if: 1) the index operation included creation of a hepaticojejunostomy or choledochojejunostomy (Table 1); 2) age was >66 years (in order to evaluate comorbidities in the year prior to the biliary-enteric bypass); 3) the patient was enrolled in Medicare part A or B for at least 12 months before and after the incident operation (or until death) and not enrolled in HMO; 4) the operation of interest was the first biliary operation to date; 5) they survived >3 months; and 6) patients were followed at least one year after the operation or until death; after one year, they were followed as long as they had Medicare claims available.

Exposure

The primary exposure was hepaticojejunostomy or choledochojejunostomy, either alone or as part of a larger operation. Type of anastomosis created was determined based on the index operation identified by CPT codes (Table 1).

Covariates

Independent variables investigated included age, gender, race, Charlson comorbidity index, operation type (hepaticojejunostomy versus choledochojejunostomy), diagnosis at surgery (benign versus malignant condition), if the patient underwent a preoperative procedure (biliary endostent or percutaneous transhepatic cholangiography) or had jaundice at the time of the index operation (defined as having a ICD-9 diagnosis for jaundice or having had undergone a preoperative biliary drainage procedure).

Outcomes

The primary outcome was hepaticojejunostomy or choledochojejunostomy stricture. Patients were identified as having a stricture if they had an ICD-9 code for biliary obstruction (576.2) OR underwent a percutaneous transhepatic cholangiography (PTC) at least 3 months after their index operation.

Other outcomes in those who developed a stricture were also examined and included: 1) time to diagnosis; 2) incidence of radiographic imaging [computerized tomography (CT) scan, percutaneous transhepatic cholangiography (PTC), magnetic resonance imaging (MRI), ultrasound (US), and endoscopic retrograde cholangiopancreatography (ERCP)] (Table 1) at least 3 months after the index operation; 3) incidence of reoperation in those with stricture diagnosis; and 4) incidence of rehospitalization related to biliary stricture by looking at primary hospitalization diagnoses of patients who were also diagnosed with a stricture.

Statistical Analysis

Descriptive statistics were done to compare patient characteristics in those who developed a stricture versus those who did not. Variables included: age, gender, ethnicity, Charlson comorbidity index, surgery type, diagnosis at surgery, and preoperative procedures. The mean, range, and median number of radiographic images depending on modality (i.e. CT-scan, versus ERCP versus PTC) were identified. Bivariate analyses including chi-square and t-tests were done to test significant differences in patients between those who developed a stricture versus those who did not. Two-year survival rates were also compared in patients with a benign or malignant diagnosis. Lastly, the mean number and range of all rehospitalizations were calculated for all patients with a stricture and all rehospitalizations related to either biliary obstruction or cholangitis.

Multivariable Analysis

Cumulative incidence curves were made to determine time to diagnosis in patients who developed a stricture. A Cox proportional hazards model was done to determine factors associated with biliary stricture. Patients were censored when they died or had no further follow-up and had not developed a stricture and were no longer “at risk”. The following covariates were included in the model: 1) age; 2) gender; 3) race; 4) Charlson comorbidity index; 5) surgery type comparing hepaticojejunostomy versus choledochojejunostomy; 6) malignant versus benign diagnosis at surgery; 7) preoperative procedure including biliary stent placement, percutaneous transhepatic drainage placement or no procedure; and 8) jaundiced at time of the index operation. Jaundice and preoperative biliary stenting were collinear and only biliary stenting was included in final model. Distance from hospital, years of education, and median household income were initially added into the model, but not found to be significant and had 150 missing observations. Therefore, those covariates were not reported.

RESULTS

Cohort Characteristics

Table 2 summarizes the overall cohort characteristics. Bivariate analysis compares patient and procedure characteristics between patients who did and did not develop a stricture. In total, 3,374 patients underwent an operation requiring either a hepaticojejunostomy (54.33%; N=1,833) or choledochojejunostomy (45.67%; N=1,541). The mean age at the time of surgery was 75.3 ± 6.2 years; 2,070 (61.3%) patients had a malignant diagnosis. After surgery, 403 patients (12%) developed a stricture. The mean time to diagnosis was 16.8 ± 21.6 months (median=8.5 month; Figure 2) with a median follow-up time of 17.8 months (IQR 7.60-48.03 months). Of those who were aged older than 75, only 10.3% (N=176) of patients developed a stricture compared to 13.7% (N=227) of patients younger than 74 years ($p=0.002$). The percentage of patients with stricture decreased as the Charlson comorbidity score increased, from 17% on those with Charlson score of 1 to only 10.5% in those with a Charlson score of 3 or more ($p=0.004$). There was no statistically significant difference in the development of stricture in those who underwent a hepaticojejunostomy versus a choledochojejunostomy (12.5% vs. 11.5%; $p=0.40$). Those with a benign condition were significantly more likely to develop a stricture compared to those with a malignant condition (61.3% vs. 38.7%; $p=0.02$), but patients who were symptomatic with jaundice at the time of their index operation were less likely to have developed a stricture compared to those who were not symptomatic (46.6% vs. 53.4%; $p<0.0001$); 2-year survival was also significantly higher in those with a benign condition compared to malignant condition (80% vs. 38%; $p<0.0001$).

Radiographic Imaging and Rehospitalization In Patients with Stricture

Radiographic imaging was done in 95.8% (N=386) of patients who were diagnosed with

a stricture. Upon diagnosis, the most common imaging modality done first was CT-scan (N=199; 53.1%) followed by PTC (N=80; 21.3%). Starting three months after their index operation (Table 3), 93.1% of patients who developed a stricture underwent CT-scan and 51.9% (N=209) of patients who developed a stricture had a percutaneous transhepatic cholangiography (PTC) done; 28.8% (N=116) of patients underwent an ERCP. Patients with a stricture were least likely to have undergone a MRI (N=75; 18.6%). Also, 53% (N=61) of patients who initially underwent a ERCP subsequently required a PTC within one week of their ERCP. Patients diagnosed with a stricture were significantly more likely to undergo an imaging procedure, regardless of modality (ERCP, $p<0.001$; MRI, $p=0.02$; US, $p=0.001$; CT $p=0.02$; PTC, $p<0.001$, Table 3). The average number of imaging modalities done per patient was also higher in those with a stricture diagnosis versus those without. (ERCP: 0.50 vs. 0.02; MRI: 0.29 vs. 0.11; US: 1.41 vs. 0.62; CT 4.22 vs. 2.51; PTC: 1.23 vs. 0; Figure 3).

In addition to high incidence of radiographic imaging in these patients, almost all patients required at least one hospitalization during the study period (N=385; 95.6%). The most common diagnosis was cholangitis (N=94). Rehospitalization in a patient with a stricture ranged widely from 1 to 36 hospitalizations (median = 4.00 rehospitalizations). Rehospitalization with a diagnosis of either biliary obstruction or cholangitis ranged from 1 to 14 (median= 2.14 rehospitalizations). Only 18 (4.5%) patients required definitive reoperation during the study period.

Factors Associated with Stricture Development

Based on a Cox proportional hazards model, the presence of a preoperative biliary endostent (HR 1.66; 95% CI 1.35-2.04) was associated with stricture formation whereas younger age was associated with a decreased likelihood of stricture formation (HR 0.98; 95% CI 0.96-

0.99); preoperative PTC (HR 1.21; 95% CI 0.66- 2.23) was not. Other factors including operation type, diagnosis type, gender, and comorbidities were not found to be significantly associated with stricture formation (Table 4).

DISCUSSION

Our study is the first to describe the incidence of biliary-enteric stricture following biliary-enteric anastomosis using a national database and the burden this has on patients and the healthcare system using a national database. The incidence of stricture following biliary-enteric anastomosis is relatively high at 12% of our cohort. Although not statistically significant, it is important to note that a greater proportion of patients who underwent an operation for a benign diagnosis were more likely to develop stricture. The reason for this may be that a greater proportion of patients with malignant disease have dilated ducts reducing the likelihood of stricture development. Also, many patients with a malignant diagnosis had poor survival rates and, therefore, likely die before this complication can develop. Nonetheless, once a patient is diagnosed with a biliary stricture, management of this condition remains burdensome. Frequent imaging and procedures are required, with many patients requiring several procedures. Interestingly, a third of patients underwent ERCP despite having altered anatomy that make ERCP alone technically difficult even at specialized centers. Conversely, definitive reoperation remained uncommon with only 5% of patients diagnosed with stricture undergoing a repeat operation.

The range of reported stricture rates varies widely across the literature. One of the larger single-institution retrospective studies included 1,595 patients who underwent pancreatic resection for malignant and benign disease, and reported an incidence of hepaticojejunostomy stricture formation in only 2.6% of patients (N=42).¹² Yet, a smaller study done by Tocchi and

colleagues⁶ followed 84 patients who underwent biliary-enteric anastomosis with 12% (N=10) of patients developing a stricture and another study included 122 patients undergoing pancreaticoduodenectomy for benign disease with a similar stricture rate of 8%.¹³ One of the higher stricture rates was reported by Kim and colleagues¹⁴ who followed 34 adult patients who underwent hepaticojejunostomy for choledochal cyst; 24% (N=8) of patients developed a stricture. Our incidence is similar to some reported studies at 12%, but also provides greater power given the larger sample size and greater generalizability given the use of a national database.

Significant factors associated with stricture formation remain inconclusive in the literature as well, but are commonly linked to preoperative and/or postoperative procedures. The aforementioned study following 1,595 patients reported on univariate analysis that preoperative percutaneous biliary drainage and preoperative endostent were associated with stricture formation; postoperative percutaneous biliary stenting was as well. In their multivariate model, these factors were not significant; this is likely because of the 1,595 patients in the study, only 42 had been diagnosed with a stricture.¹² Another study between 1988 and 2009 included 79 patients who had a biliary-enteric anastomosis related to benign disease; on univariate analysis preoperative stent placement and preoperative drainage did not show an increased odds of developing an anastomotic stricture.¹⁵ These associations were likely not significant given the small sample size and lack of statistical power. Our multivariable analysis had shown that preoperative biliary stent was significantly associated with stricture formation, likely due to our larger sample size, whereas we did not find preoperative PTC placement increasing the risk of stricture formation. Like previous studies these results were likely due to small sample size. Nonetheless, our data show that risk of stricture formation is increased with preoperative stent

placement, which may be a result of interrogation of the biliary tree compromising blood flow or introducing infection with stent placement.

Age was another significant factor associated with stricture formation; specifically younger patients were more likely to develop a stricture. This is likely secondary to younger patients having more time “at risk” given the average time to stricture formation was 17 months (median=9 months). Other studies have reported wide ranges for time to diagnosis, anywhere from 13 months to 5 years.^{4,12-14} Given these strictures commonly develop later in the postoperative period, those with malignant disease and who are older may be less likely to experience this complication.

Fortunately, reoperation for this complication remained low, but use of radiographic imaging was far greater in those with stricture diagnosis. The average number of scans per patient in those with a diagnosis was 4 scans per patient; invasive procedures such as PTC were less common but nonetheless burdensome. Interestingly, our study reports that 30% of patients underwent ERCP and 53% of these patients subsequently required a PTC within seven days after their ERCP. These findings may reflect an overall trend in healthcare to less invasive therapies, when available. Newer endoscopic techniques including single- and double-balloon enteroscopy with assisted-ERCP have been reported, but these reports come from specialized centers and our high rates of ERCP may be more indicative of unclear understanding of patient anatomy rather than newer specialized techniques.^{9-11,16} Nonetheless, gaining better understanding and utilization of these newer, less invasive techniques may provide a definitive alternative for patients with stricture, especially given these patients are older and surgery may not be a feasible option.

Overall, our study provides a description of current management in patients who develop a stricture. In the individual situation, definitive management recommendations once strictures occur largely depend on their index operation, clinical presentation at the time of presumed stricture diagnosis, benign or malignant diagnosis, prognosis, and local expertise. However, our data support several specific management recommendations. First, CT, MRI, or US can be used to diagnose biliary obstruction, and are reasonable first line studies. Second, our data confirm single-institution data on benign biliary strictures, demonstrating that non-operative management is first line therapy. Our data also reflect lack of knowledge of the anatomy after biliary enteric bypass. ERCP outside of specialized centers with very experienced interventional endoscopists is not indicated given altered anatomy; it is rarely therapeutic or diagnostic as demonstrated by the fact that more than half of patients who underwent initial ERCP went on to require percutaneous transhepatic drainage. Percutaneous transhepatic cholangiography not only provides diagnostic information, it is therapeutic in patients presenting with cholangitis, and is the interventional procedure of choice. Based on these data, we have derived a management algorithm in the work up of patients following biliary-enteric anastomosis with a presumed postoperative stricture (Figure 4). Lastly, avoidance of preoperative biliary stenting, when appropriate, may have long-term benefits. However, the indication for stenting is not easily identified in our data and significant selection bias may exist.

Given there is selection bias within this retrospective cohort; it remains a limitation of our study, especially when studying surgical patients. The use of the Medicare database is limited to claims data and older patients meaning patients were more likely to have a malignant diagnosis compared to a younger cohort and also have shorter survival. Furthermore, claims data cannot delineate details of the operation itself. It is at the discretion of the surgeon whether the patient

will be operated upon and doing a retrospective analysis cannot fully identify operative indications. Also we are unable to control for exposure, specifically operative technique. Factors such as type of anastomosis created (running versus interrupted suture, type of suture, length of roux-en-y limb) may play a significant role in stricture formation and something we cannot identify based on claims data.

CONCLUSIONS

Stricture following biliary-enteric anastomosis has a relatively high incidence in older patients. Once stricture develops, many of these patients are at high risk of requiring frequent radiographic imaging, interventions, rehospitalization, and reoperation. Further work is required to better understand both patient and physician factors that predispose patients to stricture formation, but also newer techniques created to manage these patients after diagnosis and help minimize the morbidity that is associated with stricture development.

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FIGURE LEGENDS

Figure 1. Cohort selection diagram for patients undergoing biliary-enteric anastomosis between 1996 and 2011.

Figure 2. Cumulative incidence of biliary-enteric stricture after biliary-enteric anastomosis. Mean time to diagnosis was 16.8 ± 21.6 months (median=8.5 months). Cumulative incidence of stricture formation was 12.5%.

Figure 3. Average number of imaging modalities done per patient with a hepaticojejunostomy or choledochojejunostomy stricture versus those without a stricture. (Endoscopic retrograde cholangiopancreatography= ERCP; magnetic resonance imaging=MRI; ultrasound=US, computerized tomography= CT; percutaneous transhepatic cholangiography= PTC)

Figure 4. Proposed management algorithm of patients presenting following creation of a biliary-enteric anastomosis. Depending upon patient's presenting use of MRCP or PTC are reasonable studies in the evaluation of anastomotic stricture.

Table 1. Current Procedural Terminology (CPT) and International Classification of Diseases-9th Edition (ICD-9) procedure codes for identifying primary biliary operation and radiographic imaging in patients who underwent biliary-enteric anastomosis

	<u>CPT/ICD-9 Codes</u>
<u>Procedure</u>	
Excision of bile duct tumor, with or without primary repair of bile duct	47711, 47712
Excision of choledochocyst	47715
Anastomosis biliary ducts and GI tract	47760, 47765, 47780, 47785
Whipple	48150
Whipple, but without pancreaticojejunostomy	48152
Pancreatectomy	48153, 48154, 48155, 48169
Hepaticojejunostomy	51.37
Choledochoenterostomy	51.36
Other bile duct anastomosis	51.39
Repair of other bile ducts/Excision of other bile duct	51.79/51.69
<u>Radiographic Imaging</u>	
Percutaneous Transhepatic Cholangiography (PTC)	47500, 46505, 47510, 47511, 47525, 47530, 47555, 47556, 97.05, 97.55
CT-Scan	74176, 74177, 74178, 74150, 74160, 74170, 74174, 74175, 75635, 88.38, 88.01, 88.02
Magnetic Resonance Imaging (MRI)	74181, 74182, 74183, 74185
Ultrasound	76700, 76705, 76770, 76775, 88.76, 88.74
Endoscopic Retrograde Cholangiopancreatography (ERCP)	43260, 43261, 43262, 43263, 43624, 43265, 43268, 43269, 43271, 43272, 43275, 43276, 43277, 43278

Table 2. Cohort characteristics of patients who underwent biliary-enteric anastomosis comparing those who did and did not develop an anastomotic stricture

	Overall Cohort N (%) N=3374	No Stricture N (row %) N=2971	Stricture N (row %) N=403	p-value
<u>Age Group</u>				
66-74	1659 (49.2)	1432 (86.3)	227 (13.7)	0.002
≥75	1715 (50.8)	1539 (89.7)	176 (10.3)	
<u>Gender</u>				
Male	1452 (43.0)	1267 (87.3)	185 (12.7)	0.21
Female	1922 (57.0)	1704 (88.7)	218 (11.3)	
<u>Race</u>				
White	3016 (89.3)	2654 (89.3)	362 (89.0)	0.92
Black	191 (5.7)	170 (5.7)	21 (5.2)	
Other	167 (5.0)	147 (5.0)	20 (5.8)	
<u>Charlson Comorbidity Index</u>				
0	128 (3.9)	106 (82.8)	22 (17.2)	0.004
1	426 (12.6)	360 (84.5)	66 (15.5)	
2	666 (19.7)	578 (86.8)	88 (13.2)	
≥3	2154 (63.8)	1927 (89.5)	227 (10.5)	
<u>Surgery Type</u>				
Hepaticojejunostomy	1541 (45.7)	1349 (87.5)	192 (12.5)	0.40
Choledochojejunostomy	1833 (54.3)	1622 (88.5)	211 (11.5)	
<u>Diagnosis at Surgery</u>				
Benign	1304 (38.7)	1127 (86.4)	177 (13.6)	0.02
Malignant	2070 (61.3)	1844 (89.1)	226 (10.9)	
<u>Jaundice at Surgery</u>				
Yes	1283 (38.0)	1095 (85.4)	188 (14.6)	<0.0001
No	2091 (62.0)	1876 (89.7)	215 (10.3)	
<u>Preoperative Procedure</u>				
None	2127 (63.0)	1907 (64.2)	220 (54.6)	0.0004
Percutaneous transhepatic catheter/drain (PTC)	100 (3.0)	89 (3.0)	11 (2.7)	
Endoscopic biliary stent	1147 (34.0)	975 (32.8)	172 (42.7)	

Table 3. Radiographic imaging done in patients with biliary-enteric anastomotic stricture versus those without a stricture at least three months following the index operation (N=403)

	No Stricture N=2971	Stricture N=403	p-value
	Imaging Frequency N (%)	Imaging Frequency N (%)	
<u>Imaging Modality</u>			
Percutaneous Transhepatic Cholangiography (PTC)	0 (0%)	209 (51.9%)	<0.0001
CT-scan	2071 (69.7%)	375 (93.1%)	<0.0001
Ultrasound	974 (32.8%)	228 (56.6%)	<0.0001
Magnetic Resonance Imaging (MRI)	214 (7.2%)	75 (18.6%)	<0.0001
Endoscopic Retrograde Cholangiopancreatography (ERCP)	40 (1.4%)	1166 (28.8%)	<0.0001

Table 4. Cox proportional hazards model identifying factors associated with development of biliary-enteric anastomotic stricture following biliary-enteric anastomosis

	Risk of Stricture
	Hazard Ratio (95% CI)
<u>Age</u>	0.98 (0.96-0.99)
<u>Gender (Ref: Female)</u>	1.12 (0.92-1.37)
<u>Race (Ref: African American)</u>	
White	0.93 (0.60-1.45)
Other	0.95 (0.52-1.75)
<u>Charlson Comorbidity Index (Ref: ≥ 3)</u>	
0	1.25 (0.80-1.70)
1	1.26 (0.96-1.67)
2	1.12 (0.88-1.44)
<u>Surgery Type (Ref: Choledochojejunostomy)</u>	
Hepaticojejunostomy	1.13 (0.88-1.44)
<u>Diagnosis at Surgery (Ref: Malignant)</u>	
Benign	1.13 (0.91-1.40)
<u>Preoperative Procedure (Ref: None)</u>	
Percutaneous transhepatic cholangiography (PTC)	1.21 (0.66-2.23)
Biliary stent	1.66 (1.35-2.04)