CLINICAL STUDY

The Utility of a Benign Biliary Stricture Protocol in Preventing Symptomatic Recurrence and Surgical Revision

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ABSTRACT

Purpose: To determine whether treating benign biliary strictures via a stricture protocol reduced the probability of developing symptomatic recurrence and requiring surgical revision compared to nonprotocol treatment.

Materials and Methods: A stricture protocol was designed to include serial upsizing of internal/external biliary drainage catheters to a target maximum dilation of 18-French, optional cholangioplasty at each upsizing, and maintenance of the largest catheter for at least 6 months. Patients were included in this retrospective analysis if they underwent biliary ductal dilation at a single institution from 2005 to 2016. Forty-two patients were included, 25 women and 17 men, with an average age of 51.9 years (standard deviation ± 14.6). Logistic regression models were used to determine the probability of symptomatic recurrence and surgical revision by stricture treatment type.

Results: Twenty-two patients received nonprotocol treatment, while 20 received treatment on a stricture protocol. After treatment, 7 (32%) patients in the nonprotocol group experienced clinical or laboratory recurrence of a benign stricture, whereas only 1 patient in the stricture protocol group experienced symptom recurrence. Patients in the protocol group were 8.9 times (95% confidence interval [CI] = 1.4–175.3) more likely to remain symptom free than patients in the nonprotocol group. Moreover, patients in the protocol group had an estimated 89% reduction in the probability of undergoing surgical revision compared to patients receiving nonprotocol treatment (odds ratio = .11, 95% CI = .01–.73).

Conclusions: Establishing a stricture protocol may decrease the risk of stricture recurrence and the need for surgical revision when compared to a nonprotocol treatment approach.

ABBREVIATIONS

OLT = orthotopic liver transplant, PSC = primary sclerosing cholangitis, PTC = percutaneous transhepatic cholangiogram

INTRODUCTION

Benign biliary strictures are a common clinical problem encountered by the interventional radiologist, most often secondary to laparoscopic cholecystectomy or orthotopic liver transplant (OLT) (1). Definitive management of biliary strictures is hepaticojejunostomy, which has an 82% patency at 7.6 years but is associated with a 9%–58% complication rate and up to a 5% mortality rate (2–7). Mortality in hepaticojejunostomy occurs early, with up to 2% of mortality occurring within the first 30 days (2,6). However, since the development of percutaneous transhepatic dilation in 1974, percutaneous techniques have become an integral part of minimally invasive stricture management with similar patency rates and fewer complications (8–13).

Percutaneous treatment of benign strictures has been at the discretion of the interventional radiologist, with no standardized approach to treatment. More recently, several institutions have adopted benign biliary stricture protocols, which outline a standardized algorithm for treating these patients. Stricture protocols begin with placement of the largest internal/external catheter allowed by the stricture for

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drainage of biliary contents and subsequent upsizing of the drainage catheter until an optimal size has been reached (8–11). Patients are then monitored for clinical and laboratory evidence of recurrent biliary obstruction. In the absence of recurrent disease, the drain is removed, and the patient is considered successfully treated. In patients with symptom recurrence after percutaneous therapy, treatment options include reentering the stricture protocol, stent placement, chronic internal/external drain placement, or proceeding to surgical revision (3,9–11).

To date, research validating the superiority of a stricture protocol compared to nonprotocol treatment of benign strictures is limited. This study was designed to determine whether a stricture protocol reduced the probability of patients experiencing symptom recurrence and requiring surgical revision compared to nonprotocol treatment. Evaluating this treatment approach could further promote a treatment that is less invasive, safer, and more versatile than surgical revision.

MATERIALS AND METHODS

Institutional review board approval was obtained, and patient medical records were reviewed in compliance with Health Care Portability and Accountability Act guidelines. This retrospective study included all patients who were diagnosed with a biliary stricture secondary to nonmalignant causes and underwent biliary ductal dilation in the interventional radiology division at a single institution from January 1, 2005, to June 30, 2016. Patients were excluded if they initiated or completed percutaneous therapy at an outside institution, if their stricture was secondary to a malignancy, if no stricture was found on cholangiography, or if they underwent percutaneous transhepatic cholangiogram (PTC) as staging for endoscopic stent placement for the treatment of primary sclerosing cholangitis (PSC). Additionally, patients were excluded if their stricture was unable to be traversed despite extensive effort. In these patients, external biliary drains were placed above the stricture to decompress the biliary system, and they underwent hepaticojejunostomy.

Patients undergoing treatment for biliary strictures during the study timeframe were identified using Picture Archiving and Communications System-integrated data mining software (Illuminate Insight; Softek, Kansas City, Kansas). Patients were then categorized based on their method of treatment (protocol or nonprotocol treatment), and rates of subsequent complications, symptom recurrence, and surgical intervention were calculated.

A total of 128 patients received biliary interventions during the study period. Of these, 86 were excluded due to treatment being initiated or completed at an outside institution (n = 38), biliary drain placement used as staging for endoscopic stent placement for the treatment of PSC (n = 20), malignancy (n = 17), no stricture found on exam (n = 7), and inability to traverse the stricture (n = 4). Forty-two patients met inclusion criteria, 25 women and 17 men, with an average age of 51.9 years (standard deviation [SD] ± 14.6) an average Model for End-Stage Liver Disease score of 12.5 (SD ± 6.2) and a median alkaline phosphatase of 250 (interquartile range [IQR] = 145–381).

A stricture protocol was implemented at this institution in 2011 (Fig); at that time, the decision to place patients on the protocol was at the discretion of the treating interventional radiologist. From 2011 to 2014, stricture treatment transitioned from nonprotocol treatment to the benign biliary stricture protocol, and since 2014, all patients have followed the stricture protocol. All procedures were performed by 4 fellowship-trained interventional radiologists with an average of 12.5 years of experience (range, 5–21 years).

Once the biliary tract was accessed, a cholangiogram was performed to evaluate stricture severity and the degree of associated biliary ductal dilatation. An 8.5- or 10-French Ultrathane or polyethylene internal/external biliary drain (Biliary Drainage Catheter; Cook Medical, Bloomington, Indiana) was placed, and outpatients were admitted overnight for observation. Patients then returned to the interventional radiology division every 2 weeks for upsizing in 2-French intervals until reaching a maximum dilation of 18-French. Cholangioplasty with either a cutting balloon (Peripheral Cutting Balloon; Boston Scientific, Marlborough, Massachusetts) or noncompliant balloon (Mustang Balloon Dilation Catheter; Boston Scientific) was performed at each drain upsizing per operator preference. Cholangioplasty balloon diameters ranged from 5 mm to 8 mm, with increasing diameter of the balloon as drainage catheter size increased. Patients were maintained at maximal dilation for 6 months, returning for drain exchanges in 2- or 3-month intervals. Patients then underwent drain externalization and were monitored for clinical and laboratory evidence of obstruction for 1 week. In the absence of these findings, the drain was removed, and the patient was considered treated. If symptoms recurred, patients could reenter the stricture protocol or proceed to surgical revision, a decision that was guided by transplant surgeons at this institution.

Patients were followed for as long as possible through the electronic medical record from the time of biliary drain removal to the last available note. Any clinical, laboratory, or radiologic evidence of recurrent stricture during this time was considered a failure. This included pain, jaundice, elevated bilirubin, cholangitis, or radiologic evidence of stricture. For the purposes of this study, surgical intervention was considered any surgical procedure performed by a noninterventional radiologist physician intended to treat a biliary stricture within 2 years of completing treatment for a biliary stricture.

Statistical analyses were performed using SAS software (SAS Institute, Cary, North Carolina), and *P* values less than .05 were considered statistically significant. Categorical variables were summarized using frequencies and analyzed using chi-squared and Fisher's exact tests. Continuous variables were analyzed using t-tests and Wilcoxon rank-sum tests. Logistic regression models were used to determine if

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