

ORIGINAL ARTICLE

Comparing early and delayed repair of common bile duct injury to identify clinical drivers of outcome and morbidity

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Abstract

Background: Outcomes following repair of common bile duct injury (CBDI) are influenced by center and surgeon experience. Determinants of morbidity related to timing of repair are not fully described in this population.

Methods: Patients with CBDI managed surgically at a single center from January 2008 to June 2015 were retrospectively reviewed. Outcomes of patients undergoing early (≤ 48 h from injury) and delayed (>48 h) repair were compared. Predictive modeling for readmission was performed for patients undergoing delayed repair.

Results: In total, 61 patients underwent surgical biliary reconstruction. Between the early and delayed repair groups, no differences were found in patient demographics, injury classification subtype, vasculobiliary injury (VBI) incidence, hospital length of stay, 30-day readmission rate, or 90-day mortality rate. Patients undergoing delayed repair exhibited increased chance of readmission if VBI was present or if multiple endoscopic procedures were performed prior to repair. A predictive model was constructed with these variables (ROC 0.681).

Conclusion: When managed by a tertiary hepatopancreatobiliary center, equivalent outcomes can be realized for patients undergoing early and delayed repair of CBDI. Establishment of evidence-based consensus guidelines for evaluation and treatment of CBDI may allow identification of factors that drive morbidity and predict clinical outcomes in this population.

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Introduction

Injury to the extrahepatic biliary tree is a well-described complication of cholecystectomy.^{1,2} Though a recent publication describes a decreasing rate of CBDI associated with laparoscopic cholecystectomy,³ CBDI remains a serious concern for patients and surgeons. Despite studies identifying patient^{1,4,5} and surgeon-related^{5–7} factors associated with CBDI including inflammation and conversion to open cholecystectomy,

approximately 30% of CBDI are not identified during the index operation⁸ and may not be recognized until several days after the initial injury.

While the Strasberg-Bismuth injury classification system standardizes the anatomical description of biliary injuries^{2,9} with added descriptions of *vasculobiliary injury* (VBI)^{5,10} and *extreme* VBI,¹¹ no injury description model describes the optimal time for repair of injury based on injury type or severity. In patients with suspected or identified injury, additional surgeries or endoscopic procedures may be required to diagnose the injury, to treat acute intra-abdominal processes such as biliary peritonitis, and to definitively treat biliary injury with reconstitution of

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bilioenteric flow. Each additional procedure adds to the health-care cost and presents a procedure-related risk of adverse events, and the deleterious effects on patients' quality of life (QOL) have been shown to extend dramatically beyond the acute injury and treatment phases.^{12,13} Both early and delayed repair of CBDI are described. Because no guideline exists to guide the timing of repair, the decision for timing of repair in a patient equally eligible for early or delayed repair should be based on the predicted success of the procedure and patient safety. If equivalent technical and morbidity outcomes can be achieved, patient quality of life and efficient healthcare resource utilization should be considered.

Given the frequency with which cholecystectomy is performed worldwide, even a low rate of CBDI presents a tremendous potential healthcare burden. Previous studies of CBDI have identified several factors associated with successful repair. These include treatment by an experienced hepatopancreatobiliary (HPB) surgeon and specialized center as well as multidisciplinary perioperative care.^{9,14–16}

Many patients with bile duct injuries are referred for surgical evaluation and intervention to Carolinas Medical Center (CMC), which serves as the central HPB referral center for a 48-hospital healthcare system spanning four states in the southeastern United States. The aim of this paper is to examine the CMC experience with repair of CBDI and to analyze outcomes in patients undergoing acute and delayed repair of CBDI.

Methods

Institutional Review Board (IRB) approval was obtained for retrospective data analysis. Institutional records were queried to identify patients with the diagnosis of CBDI by use of International Classification of Diseases (ICD)-9 codes at a single center from January 1, 2008, to June 30, 2015. Duplicate records were eliminated and individual records were reviewed individually to confirm that all patients included were treated for CBDI. All surgical procedures were performed by one of five attending HPB surgeons.

Patient records were retrospectively entered into a web-based, secure, HIPAA-compliant database. Patient demographics, time elapsed from index procedure, operative findings including injury classification and procedural variables, and postoperative course including 30-day readmission and 90-day mortality were recorded. Frequency of radiographic and endoscopic biliary instrumentation prior to and following definitive repair was recorded. CBDI type was reported according to the Strasberg-Bismuth classification system.^{2,9} To determine presence of VBI, radiographic images were reviewed and intraoperative ultrasound (IOUS) findings describing hepatic vascular flow were obtained from operative notes. Immediate intraoperative CBDI repairs were assessed with IOUS for VBI, while patients transferred acutely after suspected injury or repaired in delayed fashion were assessed with triphasic computed tomography (CT) imaging of the liver to determine the presence of vascular injury.

Any patient with hemodynamic instability on arrival underwent operative exploration prior to imaging.

Patients were divided into two groups based on the timing of definitive biliary repair or reconstruction: acute (≤ 48 h from index procedure) and delayed (>48 h after index procedure). Continuous and categorical variables were presented as medians and ranges and counts and percentages, respectively. Comparative analysis of continuous variables was performed using Wilcoxon rank-sum test procedure, and categorical variables using Fisher's exact test. All values were considered statistically significant at the $P < 0.05$ level. Statistical analyses were performed with Stata software version 13 (StataCorp LP, College Station, Texas, USA).

To determine the effect of delayed intervention on comorbidity, injury type, and readmission, patients in the delayed repair cohort were subdivided according to 30-day readmission status, and univariate analyses were used to test all independent variables against the binary 30-day readmission outcome. Variables analyzed for correlation included patient demographics, injury subtype, presence of vascular injury, chronic medical conditions, medications, intraoperative details of the biliary reconstruction surgery, number of therapeutic endoscopic retrograde cholangiopancreatography (ERCP) procedures >1 , presence of VBI, requirement for percutaneous transhepatic cholangiography (PTC) or transabdominal drain, and hospital length of stay. Values of $P < 0.25$ indicated significance. A multiple logistic regression model was then constructed using values identified as significant on univariate analysis. Further stepwise backward elimination with $P < 0.10$ was performed, and a Homer–Lemeshow test statistic was used to determine the goodness-of-fit of the model.

Using the coefficients generated for the independent variable of 30-day readmission as well as overall model coefficient, a predictive algorithm was generated. To determine the model's predictive accuracy, the individual probability of 30-day readmission for each record was calculated and compared to observed 30-day readmission. Each individual's resultant expected probability of readmission was recorded, and Brier scores and receiver operating characteristic (ROC) curves were generated to determine the ability of the model to discriminate true-positive results and false-positive results as well as the overall predictive capacity of the model. A readmission score was created according to the final logistic regression model. The ERCP variable was stratified according to number of procedures (1 or ≥ 2). Odds ratio (OR) values of the VBI and ERCP category variables were rounded to the nearest whole integer, and a value of one was subtracted. These scores were assessed using ROC with an area under the curve (AUC) of >0.70 considered to represent a feasible model.^{17–19}

Results

During the study period, 81 patients were evaluated for CBDI. Of these, 20 patients were excluded from further analysis: 17 were

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