

## ORIGINAL ARTICLE

# A nationwide assessment of outcomes after bile duct reconstruction

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## Abstract

**Background:** Bile duct reconstruction (BDR) is used to manage benign and malignant neoplasms, congenital anomalies, bile duct injuries and other non-malignant diseases. BDR outcomes overall, by year, and by indication were compared.

**Methods:** Retrospective analysis of Nationwide Inpatient Sample discharges (2004–2011) including ICD-9 codes for BDR. All statistical testing was performed using survey weighting. Univariate analysis of admission characteristics by chi square testing. Multivariate modelling for inpatient complications and inpatient death by logistic regression.

**Results:** Identified 67 160 weighted patient admissions: 2.5% congenital anomaly, 37.4% malignant neoplasm, 2.3% benign neoplasm, 9.9% biliary injury, 47.9% other non-malignant disease. Most BDRs were performed in teaching hospitals (69.6%) but only 25% at centres with a BDR volume more than 35/year. 32.3% involved  $\geq 1$  complication, and 84.7% were discharges home. There was a 4.2% inpatient death rate. The complication rate increased but the inpatient death rate decreased over time. The rates of acute renal failure increased. Significant multivariate predictors of inpatient death include indication of biliary injury or malignancy, and predictors of any complication include public insurance and non-elective admission.

**Conclusion:** This is the first national description of BDRs using a large database. In this diverse sampling, both procedure indication and patient characteristics influence morbidity and mortality.

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## Introduction

The term bile duct reconstruction (BDR) encompasses a variety of surgical procedures with one overarching purpose: to restore the natural flow of bile from the liver to the intestines. The indications for BDR are numerous, ranging from biliary trauma to malignancy to non-malignant diseases to congenital problems. However, the national rate of BDRs in the United States is unknown.

The literature on outcomes for BDR is sparse and mostly limited to small, single-centre studies that evaluate particular types of reconstructions in specific populations.<sup>1–4</sup> A great deal of the literature using nationwide data has focused on biliary

tract malignancies<sup>5,6</sup> and the prevention<sup>7</sup> or changing management of bile duct injuries.<sup>8,9</sup>

As the first investigation at the national scale of admissions for BDRs of all types, we aim to characterize the population receiving these procedures, identify trends in BDR and distinguish factors associated with worse inpatient outcomes.

## Patients and methods

### Patient population

A retrospective, population-based analysis was performed using discharge records from the Nationwide Inpatient Sample (NIS) for the years 2004–2011. As the largest national hospital inpatient administrative database in the US, the NIS provides a 20% sample of short-term, non-federal hospitals, amounting to 40 million weighted admissions annually.<sup>10</sup>

This study was presented at the Annual Meeting of the AHPBA, 11–15 March 2015, Miami, Florida.

Inclusion criteria were patient age  $\geq 18$  years and an ICD-9 procedure code suggestive of BDR: 51.36, 51.37, 51.39 (choledochostomy), 51.69, 51.63 (excision of bile duct), 51.72, 51.79 (choledochoplasty), 51.93 (closure of biliary fistula) and 51.94 (revision of biliary anastomosis). Exclusion criteria included any diagnosis code of liver transplant or associated transplant complications. Admissions with missing data for age, gender, inpatient death, length of stay (LOS), elective status and hospital information were also excluded.

### Patient and hospital characteristics

Patient characteristics of interest were gender, age, race, quartile for median household income based on the patient's ZIP code, insurance status, concomitant diagnoses and the Elixhauser comorbidity score, calculated using the Healthcare Cost and Utilization Project Comorbidity Software, Version 3.7.<sup>11</sup> Hospital characteristics included teaching status and annual BDR volume. High BDR volume hospitals were those in the top tertile of facilities included, defined as those performing  $> 25$  BDRs per year.

### Admission characteristics

Admissions were divided into five hierarchical groups based on the indication for BDR: congenital anomaly (including choledochal cyst), malignant neoplasm, benign neoplasm, bile duct injury or trauma and other non-malignant disease. A malignant neoplasm refers to any primary or secondary malignant neoplasm or neoplasm of uncertain behaviour, including carcinoma *in situ* and malignancies of the liver, biliary system, stomach, pancreas, small intestine, large intestine, spleen, retroperitoneum and abdominal lymph nodes. The 'other non-malignant disease category' included strictures, non-malignant obstructions and non-congenital cysts, as well as any remaining non-malignant biliary processes. Dual diagnoses were not permitted, and admission indications were categorized based on the aforementioned hierarchy. Please refer to Appendix A1 for a list of ICD-9 codes by procedure and diagnosis.

Admissions were further characterized by year range (2004–2006, 2007–2009 and 2010–2011) as well as urgency of admission. Imaging type, including intra-operative cholangiogram (IOC) or biliary X-ray, endoscopic retrograde cholangiogram (ERC) or endoscopic retrograde cholangiopancreatography (ERCP), diagnostic ultrasound, CT scan, MRI or magnetic resonance cholangiopancreatography (MRCP), performed during a BDR-related admission was identified by ICD-9 code.

### Outcomes

Outcomes of interest included inpatient complications (listed in Appendix A1) and mortality, LOS, disposition status and cost, which was determined using supplemental NIS HCUP Cost-to-Charge Ratio files.<sup>12</sup>

### Statistical analysis

All statistical analysis was performed using the weighted survey methods in SAS (version 9.3/9.4; SAS Institute, Cary, NC, USA), and all amounts reported are weighted values. *P*-values of  $< 0.05$  were considered significant. Continuous variables were divided into categories based on clinical significance. Univariate analysis was performed using chi-square tests. The Cochran–Armitage trend test was used to assess for trends over time across year groups.

A subset analysis comparing outcomes in BDRs performed with hepatectomies (ICD-9 procedure codes 50.22 or 50.3) and without hepatectomies for malignant neoplasm was performed.

Logistic regression models were created for inpatient death and any complication. Covariates were included in the models based on an univariate screen, with confounding prioritized over collinearity in the process of model building. Considered for insertion into the models were: indication, BDR procedure, gender, race, income quartile, insurance type, age category, Elixhauser score, elective status, hospital teaching status, hospital volume cluster and year category. Additionally, post-operative infection, cholangitis, acute pancreatitis, acute renal failure, acute liver failure, operative bleeding, deep vein thrombosis (DVT)/pulmonary embolism (PE), acute myocardial infarction (MI) and gastrointestinal (GI) bleed were considered for insertion into the inpatient death model. Indication was collapsed into three categories (malignant, non-malignant and biliary injury/trauma) for the inpatient death model in order to avoid small cell sizes and model instability.

## Results

### Patient and hospital characteristics

Sixty-seven thousand one hundred and sixty weighted admissions in which a BDR was performed were identified over an 8-year period. One thousand six hundred and seventy-five BDRs (2.5%) were performed for congenital anomalies, 25 150 (37.4%) for malignancy, 1528 (2.3%) for benign neoplasms, 6653 (9.9%) for biliary injury/trauma and 32 155 (47.9%) for other non-malignant disease. The majority involved women (37 119, 55.3%), white patients (39 190, 58.4%) and patients with government insurance (36 540, 54.4%). The distribution for age was left-skewed, with 45.3% of patients (30 403) age 65 years or older. A plurality of BDR-related admissions (25 075, 37.3%) involved patients with an Elixhauser score of 3 or greater. 69.6% (46 743) were admissions to a teaching hospital. Please see Table 1 for a comparison of characteristics by indication. The median yearly volume of BDRs per hospital was 10, with an interquartile range of 4–35.

In the cohort of BDRs conducted for malignancy, pancreatic malignancy was the most common indication for BDR (13 590, 53.9%), followed by liver malignancy at 25.3% (6391), extra-hepatic biliary malignancy at 14.1% (3558), intra-hepatic biliary malignancy at 7.4% (1875), gallbladder malignancy at

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