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ORIGINAL ARTICLE

Bile duct surgery in the treatment of hepatobiliary and gallbladder malignancies: effects of hepatic and vascular resection on outcomes

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Abstract

Background: Resection of the bile duct is required for the treatment of cholangiocarcinoma and is sometimes indicated in resections of liver and gallbladder malignancies. The goal of this retrospective review was to characterize surgical outcomes in patients submitted to bile duct resection for malignancy when additional procedures, specifically hepatic or vascular resections, were performed.

Methods: The American College of Surgeons National Surgical Quality Improvement Program database was searched to identify a total of 747 patients who underwent: (i) biliary-enteric anastomosis (BEA) only (Group 1, $n = 266$); (ii) BEA with hepatic resection (Group 2, $n = 439$), or (iii) BEA with hepatic and vascular resection (Group 3, $n = 42$). Postoperative outcomes were compared and regression-adjusted risk factors were analysed to produce observed and expected (O/E) morbidity and mortality ratios.

Results: The performance of hepatic and vascular resections significantly increased rates of overall morbidity ($P < 0.001$) and mortality ($P = 0.021$). Risk-adjusted O/E mortality ratios in Groups 1, 2 and 3 were 1.44 [95% confidence interval (CI) 0.84–2.30], 2.16 (95% CI 1.51–2.98) and 5.92 (95% CI 2.54–11.66), respectively. Multivariate analysis identified Group 2 ($P < 0.001$) and Group 3 ($P = 0.001$) status as independent predictors of morbidity, and Group 3 status ($P = 0.008$) as independently associated with mortality. More than 30% of deaths were associated with pulmonary complications and septic shock.

Conclusions: The addition of hepatic and vascular resections to bile duct resection significantly increased morbidity and mortality. The high O/E mortality ratios for patients in Groups 2 and 3 suggest these outcomes can be improved.

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Introduction

The surgical treatment of biliary and gallbladder malignancies continues to evolve as more extensive procedures are performed in efforts to provide complete tumour extirpation with negative margins and promote longterm survival or potential cure. In the case of hilar cholangiocarcinoma, bile duct resection is required for treatment, but the addition of hepatic resection has been shown to improve oncologic outcomes with reasonable rates of morbidity and mortality.[1–5]

More recently, various authors have reported the use of vascular resection in the treatment of cholangiocarcinoma and gallbladder malignancy with mixed results.[6–12] Vascular resection is usually carried out when the primary tumour has invaded the portal vein and/or hepatic artery, necessitating the resection and reconstruction of these structures in order to obtain a negative-margin (R0) resection. These reports derive

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from specialized units and surgeons with expertise in the management of the reported malignancies and describe both perioperative outcomes and longterm overall survival. With the exception of one report,[11] information is limited to single-institution studies with small sample sizes and is subject to biases associated with the reporting institution. In addition, there have been several recent meta-analyses of the outcomes of vascular resection in hilar cholangiocarcinoma.[13–15] As a group, these studies show vascular resection to be a feasible operative strategy, but some have reported postoperative outcomes similar to those of less extensive procedures, whereas others have shown increased mortality.

The aims of this study were to examine clinical outcomes in patients undergoing biliary surgery for hepatobiliary and gallbladder malignancies and to determine the effects of additional procedures such as hepatic and vascular resection on postoperative outcomes using data from the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP).[16] Unlike data derived from specialized hepatobiliary centres, the NSQIP database represents outcomes from a variety of hospital settings with varying levels of volume and expertise and thus its data are more representative of actual practice across the USA. In addition, the results are risk-adjusted based on preoperative clinical information to facilitate the calculation of expected rates of morbidity and mortality. The secondary aim of this study was to identify independent risk factors for increased morbidity and mortality in patients undergoing bile duct resection and reconstruction with or without hepatic or vascular resection. It was hypothesized that hepatic and vascular procedures combined with bile duct reconstruction will increase the postoperative incidences of morbidity and mortality associated with surgery for biliary and gallbladder malignancies. This study sought to quantify the decrement in outcomes in a large population-based dataset and to determine if these outcomes can be improved.

Materials and methods

This study was approved by the Wake Forest University Health Sciences Institutional Review Board and the Protocol Review Committee of the Comprehensive Cancer Center of Wake Forest University.

Data source

The ACS NSQIP is a data-driven, risk-adjusted, outcomes-based programme designed to measure and improve the quality of surgical care.[16] Details regarding sampling strategy, data collection protocol, the variables collected and organization have been previously reported.[17] This study uses the 2005–2012 Participant Use Files (PUF), which contain 295 Health Insurance Portability and Accountability Act (HIPAA) complaint variables on 543 885 surgical patients.

Study design

Patients older than 16 years of age were identified using Current Procedural Terminology (CPT) codes for biliary-enteric anastomosis (BEA), hepatic resection and vascular resection (Appendix S1, online). The codes were then correlated with International Classification of Diseases, Ninth Revision (ICD-9) codes for biliary and gallbladder malignancies (Appendix S1). Patients were then grouped into three categories based on their CPT codes according to whether they underwent BEA only (Group 1), BEA with hepatic resection (Group 2), or BEA with hepatic and vascular resection (Group 3). All patients in these three groups had a diagnosis equivalent to one of the ICD-9 codes described above.

In order to reduce confounding and create a study population that represented the inherent risks associated with the procedures specifically selected based on CPT codes for this study, patients with CPT codes that referred to major surgical procedures other than those covered in the present three procedure groups were excluded (n = 40). These included patients submitted to partial gastrectomy, partial colectomy or pancreatectomy.

Primary endpoints for this study were 30-day postoperative mortality rates, overall morbidity rates, and specific complication rates stratified by the type of procedure performed. Specific complications analysed included: cardiac arrest requiring cardiopulmonary resuscitation (CPR); deep incisional surgical site infection (SSI); organ space SSI; sepsis or septic shock; unplanned intubation; mechanical ventilation for >48 h; pneumonia; acute renal failure; progressive renal insufficiency; deep vein thrombosis (DVT); pulmonary embolus; any need for return to the operating room; superficial SSI, and urinary tract infection. Definitions of complications are based on the NSQIP Operations Manual.[17] Other covariates of interest included age, body mass index (BMI), sex, race, American Society of Anesthesiologists (ASA) physical status class,[18] smoking status (current smoker within 1 year), comorbidities (diabetes mellitus, ascites), recent weight loss (>10% of body weight in the 6 months prior to surgery), preoperative laboratory values (serum albumin and total bilirubin), and functional status (independent, partially dependent, totally dependent, unknown).

Statistical analysis

Demographic, preoperative and surgical characteristics were compared by surgical procedure group using analyses of variance (ANOVAS), chi-squared tests and Fisher's exact tests. All additional analyses were then stratified by surgical procedure. Observed and expected (O/E) morbidity and mortality ratios using validated risk-adjustment models were calculated for the overall group and by surgical procedure.[19] Observed and expected ratios were calculated using the mortality and morbidity observed, and the expected probabilities of mortality and morbidity for each patient. The expected probabilities of mortality and morbidity are included in the NSQIP database

