

ORIGINAL ARTICLE

Evaluating the American College of Surgeons National Surgical Quality Improvement project risk calculator: results from the U.S. Extrahepatic Biliary Malignancy Consortium

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Abstract

Background: The objective of this study is to evaluate use of the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP) online risk calculator for estimating common outcomes after operations for gallbladder cancer and extrahepatic cholangiocarcinoma.

Methods: Subjects from the United States Extrahepatic Biliary Malignancy Consortium (USE-BMC) who underwent operation between January 1, 2000 and December 31, 2014 at 10 academic medical centers were included in this study. Calculator estimates of risk were compared to actual outcomes.

Results: The majority of patients underwent partial or major hepatectomy, Whipple procedures or extrahepatic bile duct resection. For the entire cohort, c-statistics for surgical site infection (0.635), reoperation (0.680) and readmission (0.565) were less than 0.7. The c-statistic for death was 0.740. For all outcomes the actual proportion of patients experiencing an event was much higher than the median predicted risk of that event. Similarly, the group of patients who experienced an outcome did have higher median predicted risk than those who did not.

Conclusions: The ACS NSQIP risk calculator is easy to use but requires further modifications to more accurately estimate outcomes for some patient populations and operations for which validation studies show suboptimal performance.

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Introduction

Gallbladder cancer and extrahepatic cholangiocarcinoma are rare.^{1,2} The American Cancer Society estimated 11,420 new cases

of, and 3710 deaths, from gallbladder cancer and extrahepatic cholangiocarcinoma in 2016.³ Cure for both requires complete surgical resection with histologically negative margins.^{1,2}

Presentation: This manuscript was presented at the Americas Hepato-Pancreato-Biliary Association (AHPBA) as an oral presentation in March of 2017.

Surgical removal of many gallbladder cancers and most extrahepatic cholangiocarcinomas are operations associated with significant risk. Surgical resection for extrahepatic cholangiocarcinoma is associated with perioperative mortality of 3–17% and morbidity of 31–85%. Post-operative complications may include anastomotic leak or other deep space infection, sepsis, liver insufficiency, bleeding, venous thromboembolism, renal failure and others.^{4,5} Factors associated with perioperative complications include preoperative biliary stent, intraoperative drain placement, advanced age (>70 years) and weight loss at presentation.⁴ Postoperative complications are associated with inability to provide adjuvant therapies and worse survival.^{6,7}

The American College of Surgeons (ACS) recently established the National Surgical Quality Improvement Program (NSQIP) online risk calculator to help surgeons predict patient-specific risk for morbidity and mortality. The calculator was developed with data from 393 ACS NSQIP hospitals and was based on 1,414,006 patients including 1557 unique CPT codes. The online risk calculator allows for input of 21 preoperative factors including patient demographics and comorbidities. Data entry is a rapid process on an open and unrestricted website, and estimates of adverse outcomes are provided immediately. The model was demonstrated to have good performance for mortality, morbidity and six additional complications and performs similarly to other procedure-specific risk calculators.⁸ The objective of this study is to assess use of the ACS NSQIP calculator for patients undergoing operation for gallbladder cancer and extrahepatic cholangiocarcinoma.

Patients and methods

The United States Extrahepatic Biliary Malignancy Consortium (USE-BMC) is a group of 10 U.S. academic medical centers (The Ohio State University, Columbus, Ohio; Emory University, Atlanta, Georgia; University of Wisconsin, Milwaukee, Wisconsin; Johns Hopkins University, Baltimore, Maryland; Stanford University, Stanford, California; New York University, New York, New York; Washington University, St. Louis, Missouri; Vanderbilt University, Nashville, Tennessee; University of Louisville, Louisville, Kentucky; Wake Forest University, Winston-Salem, North Carolina). A database of 1092 patients with gallbladder cancer, or distal or hilar cholangiocarcinoma, who underwent operation between January 1, 2000 and December 31, 2014 was compiled by the USE-BMC. The institutional review boards of all participating institutions approved the study.

The ACS NSQIP calculator was accessed online at <http://riskcalculator.facs.org/> on August 26th and 27th, 2016. Individual patient data and Current Procedural Terminology (CPT) codes were entered into the calculator, and estimated risks were recorded in a database for each patient, specifically estimates for surgical site infection, death, reoperation, readmission and length of stay. Estimates of risk from the calculator are presented to the user as percentage risk of the event occurring.

At the time of analysis, the calculator required entry of the following factors: procedure type, age, sex, functional status, emergency case, ASA classification, steroid use, ascites, sepsis, ventilator status, disseminated cancer, insulin and non-insulin dependent diabetes mellitus, hypertension, congestive heart failure, dyspnea, current smoker, severe COPD, dialysis dependence, acute renal failure, height and weight. Definitions of each category may be found on the risk calculator website. For patients with a preoperative risk calculator factor missing, risk was assumed to be at the lowest risk level.

The estimated risk for each outcome was then compared to actual patient outcomes. The following calculator outcomes were included in the study: surgical site infection, mortality, readmission, return to the operating room and length of stay. Additional calculator outcomes were not analyzed as they were not included in the USE-BMC dataset. Demographics and clinical characteristics were summarized using descriptive statistics (median and range for continuous variables, frequency for categorical variables). Logistic regression models were used to determine the association between the actual outcome and the calculated risk using the ACS NSQIP calculator. The ability of the ACS NSQIP calculator to accurately predict a particular outcome was assessed using the c-statistic, also known as the area under the curve (AUC) of a receiving operating characteristic curve, and the Brier score. The Brier score simultaneously reflects discrimination and calibration and is calculated as the mean squared difference between a patient's predicted probability and observed outcome. A Brier score of 0 represents perfect prediction and the cutoff at which a model is no longer informative is determined partially based on incidence in the sample.^{9,10} Two sub-group analyses were performed, one for patients undergoing liver surgery including partial lobectomy, total left lobectomy and total right lobectomy and trisegmentectomy, and one for patients who underwent pancreas surgery including standard and pylorus-sparing Whipple procedures.

Patients were excluded who did not have complete tumor resection for cure. Also, the following operations were excluded as they are not included in the ACS NSQIP risk calculator: liver transplantation and diagnostic laparoscopy.

All statistical analyses were conducted using SAS for Windows® Version 9.2 (SAS Institute Inc., Cary, NC), although ROC curves were plotted using the pROC package in R v. 3.0.1. (Vienna, Austria).

Results

Eight-hundred and fifty-four patients with gallbladder cancer, or distal or hilar cholangiocarcinoma, who underwent curative-intent, complete resection between January 1, 2000 and December 31, 2014 was compiled by the USE-BMC (Table 1). The majority of patients underwent hepatic resection including partial lobectomy (254, 29.7%), trisegmentectomy (118, 13.8%), total left lobectomy (62, 7.3%) or total right lobectomy (41,

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