
Protocol-Driven Management of Suspected Common Duct Stones



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- BACKGROUND:** Common duct stones can be diagnosed by magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS)/ERCP, and intraoperative cholangiogram (IOC). In 2015, our group adopted a standard approach of preoperative EUS/ERCP followed by laparoscopic cholecystectomy for patients with an admission bilirubin >4.0 mg/dL. For bilirubin <4.0 mg/dL, laparoscopic cholecystectomy with IOC was the initial procedure. Postoperative EUS/ERCP with endoscopic sphincterotomy was pursued for positive IOC. Exclusions included clinical suspicion of malignancy and surgically altered anatomy making endoscopic management impractical.
- STUDY DESIGN:** A retrospective comparison of protocol and pre-protocol (baseline) patients was performed, looking at patient demographics, presence of pancreatitis, common duct stone factors, comorbidities, length of hospitalization, and postoperative morbidity. Statistical analysis was performed with *t*-test, chi-square, and Wilcoxon rank-sum test with significance at $p < 0.05$.
- RESULTS:** There were 56 patients in each group, with a mean \pm SD age of 50.5 ± 20.88 years and 49.3 ± 20.92 years, respectively ($p = \text{NS}$). There were no significant differences between baseline and protocol patients with respect to individual and cumulative preoperative comorbidities, pancreatitis, elevation of liver function tests, bilirubin, common duct size, and postoperative morbidity. There were fewer endoscopies (22 vs 35; $p = 0.014$), and shorter length of stay in protocol patients (2.8 days vs 3.8 days; $p = 0.025$).
- CONCLUSIONS:** Protocol-driven management of patients with suspected common duct stones reduced the number of endoscopies and length of hospitalization, with no change in postoperative morbidity. This approach has the potential to decrease endoscopy-related morbidity and overall cost without affecting quality of care. (J Am Coll Surg 2017;224:645–649. © 2017 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)
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The incidence of common bile duct stones in patients ranges from 5% to 18% of patients presenting with cholelithiasis/cholecystitis.^{1,2} The diagnosis and management of common duct stones has evolved since the advent of laparoscopic cholecystectomy. Before 1990, open

cholecystectomy with intraoperative cholangiogram was the primary diagnostic modality. Open common duct exploration was the procedure of choice if common duct stones were identified. With the advent of laparoscopic cholecystectomy, postoperative ERCP largely replaced common duct exploration for management of common duct stones. This approach has been successful in >95% of patients.³ With this change in management, there was also a shift toward preoperative identification and clearance of common duct stones. Endoscopic ultrasound (EUS), ERCP, and magnetic resonance cholangiopancreatography (MRCP) are often performed preoperatively in patients with risk factors for common duct stones. However, despite this shift in management, questions remain about the optimal management of this patient population. Some argue that proceeding immediately to laparoscopic cholecystectomy (LC) with intraoperative cholangiography (IOC) is the best step, with

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Abbreviations and Acronyms

ES	= endoscopic sphincterotomy
EUS	= endoscopic ultrasound
IOC	= intraoperative cholangiography
LC	= laparoscopic cholecystectomy
MRCP	= magnetic resonance cholangiopancreatography

further endoscopic measures based only on a positive IOC.⁴ Others have proposed that IOC has become obsolete in the era of ERCP and/or MRCP.⁵

The risk factors for common duct stones have historically included elevated bilirubin, clinical jaundice, pancreatitis, a dilated common duct on imaging, elevated liver function tests, and small stones within the gall bladder. These risk factors are imperfect indicators of common duct stones and have yielded positive cholangiography in 10% to 60% of patients. When these risk factors are used to perform preoperative imaging, the majority of patients will have negative studies. It could be argued that a negative preoperative ERCP/MRCP is an unnecessary test and adds to the length of hospitalization and cost of care. Before 2015, our acute care surgery group had varying practices for preoperative imaging of the common duct by ERCP or MRCP. In 2015, our group adopted a protocol-driven approach to suspected common duct stones. Preoperative evaluation of common duct stones by ERCP or MRCP was used only for patients who had a total bilirubin >4 mg/dL at time of presentation, suspicion of malignancy, or surgically altered anatomy, such as a Roux-en-Y gastric bypass. For all other patients, initial treatment was LC with selective IOC based on preoperative risk factors. This study represents an analysis of our protocol-based management and compares it with historic controls.

METHODS

Study design

An IRB-approved retrospective cohort study was performed comparing patients before and after implementation of a protocol-driven approach of suspected choledocholithiasis. Using our institution's electronic medical record (Epic, 2014), a retrospective review was performed of all patients who underwent LC on the trauma/acute care surgery service from June 1, 2014 through August 15, 2014 (baseline patients). A similar review was conducted on patients managed under the protocol after implementation in 2015 (protocol patients). All patients had either preoperative, and/or intraoperative imaging of the common duct. Common duct stones were managed by endoscopic sphincterotomy (ES), stone

Table 1. Patient Demographics, Median Bilirubin, Common Duct Size, and Presence of Pancreatitis

Characteristic	Baseline	Protocol	p Value
Total patients, n	56	56	
Age, y, median \pm SD	49 \pm 20.92	50 \pm 20.88	0.756
Bilirubin, mg/dL, median \pm SD	2.34 \pm 1.45	2.68 \pm 2.2	0.691
Common bile duct size, mm, median \pm SD	6.6 \pm 2.75	7.0 \pm 2.47	0.289
Pancreatitis, n	15	16	0.832

extraction, with or without stent placement. No common duct explorations were performed during the study.

Before the protocol, physician discretion determined which patients would undergo preoperative imaging of the common duct by EUS/ERCP or MRCP. There were differing thresholds for preoperative imaging by our acute care surgeons, and the criteria for preoperative imaging consisted of varying combinations of risk factors for common duct stones. After initiation of the protocol, preoperative imaging was reserved for patients with a preoperative bilirubin >4.0 mg/dL. Patients were excluded from the protocol if there was clinical suspicion of malignancy, or surgically altered anatomy, such as a Roux-en-Y reconstruction.

Data collected included date of initial surgery, age, sex, preoperative comorbidities, admission diagnosis (cholecystitis vs pancreatitis), maximum bilirubin, presence/absence of increased liver function studies, common bile duct diameter (measured using ultrasound), interval from initial evaluation to initial intervention, type of initial intervention (endoscopy vs surgery), length of stay, postoperative morbidity and mortality. A total of 56 baseline and 56 protocol patients were included in the final analysis. The primary end point under investigation was length of stay. Secondary outcomes included number on endoscopies, postoperative morbidities, and mortality.

Statistical analysis included chi-square tests or Fisher's exact tests to compare nominal variables by group. A 2-sample *t*-test was used to compare normal variables by treatment. Wilcoxon-rank-sum tests were used for comparison of non-normal variables. Differences were considered significant at a *p* value of <0.05.

RESULTS

Demographics were similar in terms of age and preoperative comorbidities. Mean age was 49 \pm 20.92 years and 50 \pm 20.88 years in the baseline and protocol groups, respectively (*p* = 0.3033). Preoperative comorbidities were not significantly different. Median bilirubin (peak) was 2.34 mg/dL and 2.68 mg/dL (*p* = NS) and common

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