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ERCP and laparoscopic cholecystectomy in a combined (one-step) procedure: a random comparison to the standard (two-step) procedure

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Abstract

Background—Current treatment of complicated calculous biliary disease typically involves a two-step procedure consisting of preoperative endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic cholecystectomy. Alternatively, laparoscopic cholecystectomy with intraoperative cholangiogram (IOC) and intraoperative common bile duct exploration or ERCP at a later date may be performed. This study compared the benefits of the traditional two-step procedure to the novel one-step procedure for the management of calculous biliary disease.

Methods—A retrospective review of 20 patients was conducted comparing one-step to two-step procedures for the management of choledocholithiasis. We define the one-step procedure to be a laparoscopic cholecystectomy with IOC to confirm the presence or absence of stones. Intraoperative ERCP with stone extraction was conducted if necessary as part of the one-step procedure.

Results—A statistically significant difference existed between hospital charges for one-step ($58,145.30, SD $17,963.09) and two-step ($78,895.53, SD $21,954.78) procedures ($p = 0.033$).

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Other parameters (length of stay, preoperative days) trended toward significance; however, statistical significance was not achieved.

Conclusions—There appears to be a significant cost reduction with implementation of the one-step treatment of calculous biliary disease. Further research with a larger study population is necessary to determine the additional benefits of this procedure and to help augment the surgical endoscopists' armamentarium.

Keywords

Cholecystectomy; Choledocholithiasis; Endoscopic retrograde cholangiopancreatography (ERCP); GI endoscopy; One-step; Two-step

Gallstones exist in 15 % of the population and can lead eventually to serious complications such as cholecystitis, choledocholithiasis, and pancreatitis. In patients who require cholecystectomy for cholecystitis, 10–18 % also will exhibit choledocholithiasis. Additionally, up to 25 % of cases of choledocholithiasis may be discovered intraoperatively [1]. The current gold standard for treating acute or chronic cholecystitis is laparoscopic cholecystectomy with or without intraoperative cholangiogram (IOC) [1, 2]. As noted previously, a significant portion of these patients will also exhibit common bile duct stones, and thus a therapeutic plan must be made for this subset of patients. No single method or algorithm has been shown to be superior to others when treating the obstructing complications of calculous biliary disease that include jaundice, pancreatitis, cholangitis, and asymptomatic choledocholithiasis [1]. Traditionally, this treatment involves what is known as a two-step procedure, consisting of preoperative endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic cholecystectomy. Alternatively, laparoscopic cholecystectomy with IOC and intraoperative common bile duct exploration or ERCP performed at a later date may be performed in the traditional two-step framework [2]. We define the one-step procedure to be a laparoscopic cholecystectomy with IOC to confirm the presence or absence of stones. Intraoperative ERCP with stone extraction was conducted during that same operative time if necessary as part of the one-step procedure.

Since 1997, our group has been performing one-step procedures with great anecdotal success for select cases of obstructing biliary disease. The results of this work were presented in 1998 at the sixth World Congress of Endoscopic Surgery, and at the American Society of Gastrointestinal Surgeons (SAGES) annual conference in 2010. For the first time at this institution, a comparison of this patient population has been investigated to compare the benefits of the one-step procedure to the two-step procedure. Our objective, therefore, was to demonstrate the benefits of the one-step procedure for the definitive management of choledocholithiasis by surgeons in a single operation combining laparoscopic cholecystectomy, IOC, and intraoperative ERCP.

Materials and methods

A retrospective, single-institution review was conducted for 2009–2011. Twenty consecutive patients who had received either the one-step or two-step procedural pathway

for suspected choledocholithiasis were chosen for the study (Table 1). Patients were excluded from the pathway if the attending surgeon could not perform and supervise the one-step procedure. For this reason, all patients in this study were treated by the same surgical endoscopy attending physician. In our institution, one surgical attending physician has ERCP privileges. This physician solely conducts resident and fellow training to learn the ERCP procedure. Our group follows the guidelines of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) for ERCP proficiency. These guidelines describe a training program as including practical and didactic instruction. Trainees are also required follow the patients longitudinally and are involved in the care of all short- and long-term outcomes relating to the ERCP. The surgeon instructor allows carefully selected periods of direct operative experience in addition to simulation laboratory familiarization with the endoscopy equipment and endoscopy suite. All enrollees in this ERCP training program gain proficiency in both diagnostic and therapeutic procedures. SAGES emphasizes that performing an arbitrary number of procedures does not define proficiency, but that more importance should be placed on the completion “a significant volume” of appropriately supervised diagnostic and therapeutic ERCPs [3]. At this institution, proficiency (which allows for credentialing in diagnostic and therapeutic ERCP) is defined as having conducted 200 ERCP procedures, a number that our attending instructor’s experience far exceeds.

Patients with suspected choledocholithiasis received informed consent regarding the one-step procedure. Positioning was in the usual supine position for laparoscopic cholecystectomy. Laparoscopic cholecystectomy with operative cholangiogram was always attempted and images obtained during this step (Fig. 1).

At this time, in accordance with the one-step procedure, if the cholangiogram demonstrated filling defects in the common bile duct, the laparoscopic portion of the procedure would then be completed and the ERCP performed immediately in the supine position. The ERCP was always conducted after the laparoscopic portion of the procedure to limit lack of laparoscopic visualization as a result of bowel insufflation.

When managing calculous biliary disease in this manner, an issue that arises is that of patient positioning. The majority of endoscopists conduct ERCP in the prone or left lateral decubitus positions [4, 5]. Generally, the supine position is only advocated for use in the operating room under general anesthesia so the airway may be adequately protected. To minimize operative time and maintain endotracheal tube placement, our group has elected to conduct the ERCP as part of the one-step procedure in the supine position. Very few studies have looked into the utility of conducting ERCP in this particular manner. Ferriera et al. looked at the overall safety of conducting supine ERCP and determined that it could be conducted safely in certain patients (even nonintubated patients) in whom prone or left lateral decubitus positioning was contraindicated [4]. Wilcox et al. noted that when comparing supine to prone/decubitus positioning, both afford equivalent results in terms of procedural success [6]. In our study, we continue to illustrate our success with supine positioning in the one-step procedure

With supine patient placement and identification of common duct stones on initial imaging during ERCP (Fig. 2), papillotomy would be performed with or without stent placement, in addition to stone extraction (Fig. 3)

Finally, upon completion of the stone extraction (if required), a completion image would be obtained, noting resolution of the common bile duct filling defect and filling of the duodenum.

All cases, including the ERCP, were performed by surgical residents with close supervision of surgical endoscopist attending. Ten one-step and ten two-step procedures were conducted. The one-step procedures were conducted as described above. The two-step procedures were also conducted by surgical residents with close supervision of the surgical endoscopy attending physician. Two-step procedures, in this study, consisted of a preoperative ERCP followed by laparoscopic cholecystectomy. Alternatively, laparoscopic cholecystectomy with IOC and intraoperative common bile duct exploration or ERCP performed at a later date may have been performed. Outcome variables measured were preoperative hospital days, total operative time, additional procedures performed (if necessary), complications, length of stay, and total hospital charges.

Variables were compared by both Mann–Whitney test and one-way analysis of variance. We considered differences in categories to be statistically significant at $p < 0.05$. It is important to note that a power analysis was conducted to determine the total number of patients in each arm needed to achieve 90 % statistical power to detect a 1.5-fold difference in both the length of stay and total hospital charge variables. To achieve adequate power, it was determined that 11 patients per group would be needed to achieve this when looking at the total hospital cost outcome variable, and 18 patients per group would be needed to achieve adequate power when looking at length of stay as an outcome.

Results

When comparing the ten patients receiving one-step procedures to the ten patients receiving two-step procedures for the management of calculous biliary disease, we noticed trends in a number of the outcome variables. Significance was achieved when comparing total hospital charges in the two groups. The mean total hospital charge in the one-step group was $58,145.00 (17,963.09) and $78,895.00 ($21,954.78) in the two-step group ($p = 0.033$). We noted a trend toward decreasing preoperative days: the mean number of preoperative days spent in the hospital for the one-step patients was 2.3 days, versus 3.1 days for the two-step patients. Although this was a trend down, this category did not achieve statistical significance ($p = 0.386$). Additionally, a downward trend in overall length of stay was noted, with an average of 3.8 days spent in the hospital for the one-step arm, and an average of 5.3 days spent in the hospital for the two-step arm. Again, statistical significance was not achieved ($p = 0.110$).

It was also noted that operative time for the two-step procedure was slightly increased when compared to the one-step procedure (a nonsignificant difference). The average (standard

deviation) time for completion of the one-step procedure was 108.10 (35.53) min, while the average time completion of the two-step procedure was 117.60 (30.81) min.

There was one occasion in which a patient in the one-step group required an outpatient ERCP for a retained cystic duct stone. This was treated without incident and is documented in Table 2.

Discussion

It has been demonstrated by our group that obstructing calculous biliary disease can be effectively treated by surgeons in a one-step fashion. This treatment pathway cuts hospital costs dramatically. Evidence gained from this study and others suggests that the one-step technique may decrease length of stay as well as preoperative waiting time. In the current environment of managed care and cost containment, these are not insignificant accomplishments. A cost reduction of over $20,000 per patient was noted in this limited series alone.

Much of the existing body of literature comparing single-step management to traditional management schemes has been developed abroad by gastroenterologists. Tzovaras et al. noted significant decreases in length of hospital stay and in postoperative serum amylase values by using this method. Their group, and others [7], have termed the one-step procedure the laparoendoscopic rendezvous (LERV) technique [8]. La Greca et al. and Enochsson et al. [9, 10] also both noted success with this technique as practiced by a multi-disciplinary group comprising both surgeons and gastroenterologists. Iodice et al. [11] noted the feasibility of this one-step technique, citing shortened hospital stay as a benefit. Morino et al. [12] found that laparoendoscopic rendezvous technique (one step) allowed for a higher rate of common bile duct stone clearance in addition to decreased hospital stay and decreased cost. Lella et al. [13] noted that the LERV technique was beneficial in patients at particular risk for post-ERCP pancreatitis. Rábago et al. also compared a one-step to a two-step approach. The group receiving the one-step approach with intraoperative ERCP exhibited a decrease in morbidity in addition to shorter hospital stay and decreased hospital costs. The decrement in morbidity in the intraoperative ERCP group resulted from the lower rate of papillotomy and lower rates of post-ERCP pancreatitis and cholecystitis [14]. Del Rio et al. [15] posited that the one-step procedure improved patient compliance compared to the two-step procedure. The LERV is most commonly described in the European literature as cooperation between surgeons and endoscopists in the same operative suite [8, 16]. LERV is similar to our one-step procedure; however, with the LERV, the ERCP is not uniformly conducted in the supine position and requires repositioning, which may extend operation time. Additionally, the LERV procedure is conducted by both surgeons and endoscopists, not the same surgical endoscopist attending, as with our one-step procedure. In the United States, more work must be done to delineate the surgical endoscopist’s role in managing choledocholithiasis and obstructing calculous biliary disease in a one-step manner.

By limiting the number of operative procedures, patients can be safely and more efficiently treated using this method. Certainly the quality of these data may be improved by an increase in sample size and by expansion beyond one surgical endoscopist’s practice. The

one-step technique is simply such a novel procedure at this institution—and, we would argue, in the rest of the United States—that attempting to achieve this increased statistical power has been challenging. An institutional review board-approved, prospective, randomized, controlled study is currently underway in this institution as the one-step procedure becomes more acceptable to other attending surgeons and as our volume of these procedures increases. In this future endeavor, we hope to increase the statistical power of the study. Although we almost achieved 90 % statistical power with regard to evaluating the total hospital costs variable (ten patients per group were analyzed; 11 would be required to achieve 90 % power in resolving a 1.5-fold difference), we did not achieve an adequate sample size to resolve a significant difference in length of stay.

We also attempted to overcome other limitations associated with limited sample size. These data, for example, identifies a 10 % rate of retained stone after ERCP. Anecdotally, however, our overall retained stone rate is much lower than this—more in the vicinity of 5 %. The retained stone rate in some series has been documented to be as high as 12 % [17, 18] and as low as 2–4 % [19]. With the increased cohort of patients in upcoming studies, we hope to demonstrate that there is no increased incidence of retained common bile duct stones with the one-step procedure than what is outlined in the literature. With a prospective sample and a larger sample size, the information we may obtain will be even more useful than that obtained from the present retrospective review.

One potential area of controversy relating to the one-step procedure can be related to the use of IOC. There are many options this group could have chosen for preoperative or intraoperative diagnosis of suspected common bile duct stones. The current role of IOC is a contentious one when pertaining to the prevention of common bile duct injures and the management of common bile duct stones [20]. Uncertainty regarding the benefit of IOC leads to wide variation in use across surgeons and hospitals [21, 22]. Surgeon preference and hospital accommodations seem to be the most important determinant of IOC utilization as opposed to patient disease characteristics [23]. In the current body of literature, unsuspected stones identified on IOC ranges from 0.9 to 10 %, with most authors reporting values of 3–7 % [20]. There also is the possibility of utilizing IOC followed by stone removal via the cystic duct or common bile duct in the same operative time. This is an option that is currently practiced in many centers; however, it is not the standard of care at our institution or in our region. For this reason, conducting our stone extractions utilizing the IOC imaging alone would be difficult to bring into practice in this setting and therefore was not investigated in this study.

Radiation exposure is also a potential limitation of this process, especially given the fact that we are training residents and fellows in this procedure. Oztas et al. [24] in 2011 documented an increase in radiation exposure for trainees compared to experienced endoscopists. In any radiologic procedure involving a significant learning curve, there exists the reality of increased exposure to radiation; however, we attempt to reduce exposures by using lead protective garments including thyroid shields; by using dosimeters; and by inserting contrast media only when imaging is required. Although we collected no data on radiation exposure in this study, it is clearly an area of concern and interest to any physician involved in conducting procedures that exhibit a significant learning curve.

In the same vein of decreasing radiation exposure, certain series have also examined the use of magnetic resonance cholangiopancreatography (MRCP) in the identification of common bile duct stones [25]. This modality may be less invasive; however, problems with sensitivity and cost complicate this technique. Srinivasa et al. [26] noted that while it was successful in identifying gallstone pancreatitis, it did not offer the same success in identifying choledocholithiasis. Rahman et al. [27] noted MRCP was only 74.6 % sensitive for choledocholithiasis as compared to typically higher percentages identified for ERCP in the existing literature. In addition to data questioning the efficacy of ERCP, cost and time required to conduct the procedure become an issue with MRCP as opposed to ERCP. Given the sum of these factors, our success with IOC, and the ease of conducting an IOC during laparoscopic cholecystectomy at this institution, we have chosen this modality for initially localizing common duct calculi.

One final limitation of the methodology of this study is the ordering of the procedures in the operative engagement. The one-step group all received laparoscopic cholecystectomy first in order to avoid the poor visualization that preoperative bowel insufflation from the endoscope may have imparted. The two-step group was not exactly matched in this regard, in that the ERCP may have been conducted either before or after the laparoscopic cholecystectomy,

The future is bright regarding single-step procedures for management of calculous biliary disease. We do not advocate the routine use of intraoperative ERCP in uncomplicated laparoscopic or open cholecystectomies. In select cases, however, when indicated on the basis of intraoperative cholangiography, the one-step pathway is extremely advantageous and cost-effective.

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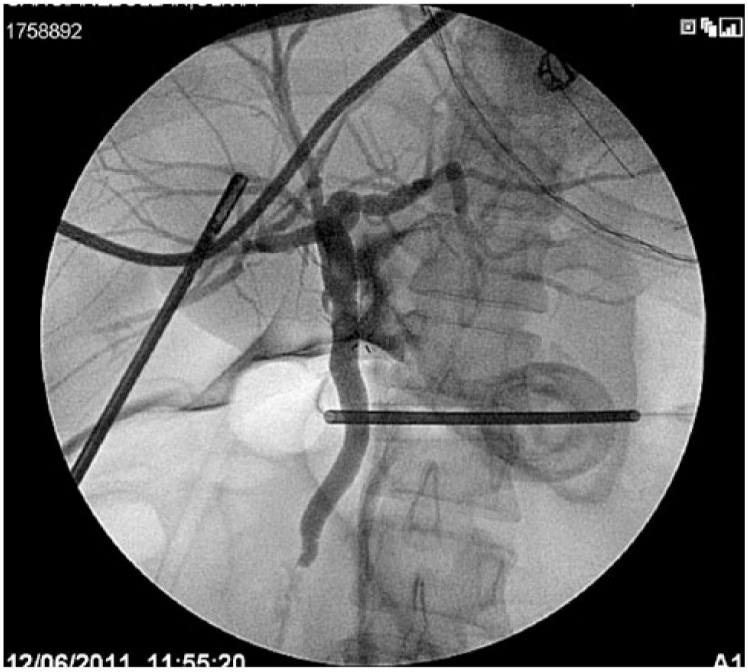

Fig. 1.
Interoperative cholangiogram image

Fig. 2.
ECRP image

Fig. 3.
Stone extraction during ERCP

Table 1

Patient demographics

Characteristic	Two-step patients	One-step patients
Sex (F/M)	10/0	9/1
Average age (year)	41.3	38.6
Age range (year)	23–56	18–64
Race/ethnicity	Nine Hispanic, one White	Seven Hispanic, two White, one Asian

Table 2

Comparison of one-step to two-step procedures for management of biliary calculi

Measure	Average value for:	
	One-step patients	Two-step patients
No. of patients	10	10
Preoperative days	2.3	3.1
Total operative time (min)	108.1	117.6
Additional procedures	1	0
Type of additional procedure	ERCP[a]	NA
Complications	0	0
Length of stay (days)	3.8	5.3
Total hospital charges	$58,145*	$78,895*

ERCP endoscopic retrograde cholangiopancreatography, **NA** not applicable

*Statistically significant ($p = 0.033$)

[a]An additional procedure was performed on a patient in the one-step group for a retained cystic duct stone. This was successfully extracted via outpatient ERCP