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Retrospective Comparison of One-stage versus Sequential ERCP and Laparoscopic Cholecystectomy in Patients with Symptomatic Gallstones and Suspected Common Bile Duct Stones

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Abstract ***Objective:*** **To establish the feasibility and the results of one stage endoscopic retrograde cholangiopancreatography (ERCP) and laparoscopic cholecystectomy (LC) compared to the sequential ERCP and LC.**

Patients and Methods: **The results in 14 patients (7 males, 7 females, mean age 56.4 years) who underwent one-stage ERCP and LC were reviewed and compared to the results of 38 patients (11 males, 27 females, mean age 57 years) who underwent sequential ERCP and LC. The success rates, postoperative complications, overall operative time and length of hospital stay were analyzed.**

Results: **The one-stage group had LC success rate of 64%, 21% postoperative complication rate, with a median operative time of 155 minutes and a median hospital stay of 7 days. The sequential group had LC success rate of 92%, 8% postoperative complication rate, with a median operative time of 137 minutes and a median hospital stay of 8.5 days.**

Conclusions: **Single stage ERCP and LC can be performed with no significant differences in the overall operative time, postoperative complication rate and length of hospital stay.**

Introduction

Choledocholithiasis occurs in 10-15% of patients with symptomatic gallstone disease.[1-3] In general, common bile duct (CBD) stones should be removed because they may be associated with complications such as gallstone pancreatitis and cholangitis.[4,5] There are many possible work up options for common bile duct stones, depending on the preferred diagnostic modality which includes endoscopic retrograde cholangiopancreatography (ERCP), intra-operative cholangiography (IOC), endoscopic ultrasonography (EUS), magnetic resonance cholangiopancreatography (MRCP), intraoperative ultrasonography (IOUS) and helical CT cholangiography (hCTC).[5-7] ERCP is useful for both diagnosis and treatment of secondary CBD stones, with stone clearance in 80-85% of patients.[8,9]

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At Ramathibodi hospital, preoperative diagnostic and therapeutic ERCP are performed under general anesthesia for suspected CBD stones in symptomatic gallstone patients. Almost all patients undergo subsequent laparoscopic cholecystectomy (LC) at another anesthetic session (sequential ERCP and LC). Failure of LC is managed by conversion to open cholecystectomy. In the literature, the order of the ERCP/LC sequence varies, with some surgeons performing ERCP before LC while others performing LC before ERCP.[8-13]

A single stage approach combining laparoscopic cholecystectomy and ERCP in the same anesthetic session has been described (one-stage ERCP and LC).[8,9,11-13] The objectives of this approach are to reduce the number of anesthetic sessions, the length of hospital stay and hospital costs. The expected drawback of this approach is the post-ERCP bowel dilatation that might interfere with the LC operation leading to more operative complications.

The aim of this study was to assess the feasibility of one-stage ERCP and LC and to compare the results with that of sequential ERCP and LC as generally practiced at Ramathibodi hospital.

Patients and Methods

Between March 2000 and December 2001, 14 patients with symptomatic gallstones underwent one-stage endoscopic retrograde cholangiopancreatography (ERCP) and laparoscopic cholecystectomy (LC). There were seven men and seven women in this group (1:1 Female to Male ratio). Thirty-eight patients who were treated with sequential ERCP and LC between January 1998 and December 2001 constituted the comparison group.

All patients were documented to have gallstones by ultrasound examination. Patients were suspected of having CBD stones if one or more of the followings were present: jaundice or acute pancreatitis on admission, previous episodes of jaundice or pancreatitis, abnormal liver function tests (elevated serum AST, ALT, GGT and bilirubin levels) and evidence of bile duct stones or dilated CBD on ultrasonogram (defined as ultrasonographic CBD size greater than 10 mm). The presence of jaundice was defined as serum bilirubin level greater than 2 mg/dL. Pancreatitis was defined as the finding of at least three folds increase in serum amylase or serum lipase.[3]

ERCP in the one-stage group was performed under general anesthesia. If CBD stones were found on endoscopic cholangiography, endoscopic sphincterotomy was then performed and the stones were extracted using a Dormia basket or a balloon catheter. Patients underwent open surgery and CBD exploration if endoscopic stone removal failed. Laparoscopic cholecystectomy was performed using the standard four port technique and CO_2 insufflation. All difficulties and complications noted during the performance of LC or ERCP were recorded. Operative time, success rate (non-conversion rate) and length of hospital stay were the outcomes of the study. Success was defined as successful LC after ERCP.

ERCP in the sequential group was also performed under general anesthesia. Nine of 38 (24%) patients were out-patients. Following ERCP, patients either underwent LC in the same admission or in another admission. The duration between the two procedures was defined as the treatment interval. LC in this group was also performed using standard techniques. The success rate, postoperative complications, operative time and length of hospital stay were recorded.

Comparison of continuous variables between two independent groups was done using unpaired Student's t-test or Wilcoxon rank-sum test, and the comparison of categorical variables was done using Chi-squared test or Fisher's exact test as appropriate. Statistical significance was set at p-value of 0.05 or lower.

Results

There were 52 patients with symptomatic gallstones in whom CBD stones were suspected. Thirty-eight patients underwent sequential ERCP and LC and 14 patients underwent one-stage ERCP and LC. Baseline characteristics to be compared included age, sex, proportion of preoperative abnormal liver function test, proportion of preoperative pancreatitis, stones seen on ERCP and associated medical diseases (Table 1). All baseline characteristics were not statistically different between the two groups.

Table 2 shows the outcomes of the study. Success rate of LC in the sequential group was 92% (35/38), and 64% (9/14) in the one-stage group ($p = 0.03$). LC in five patients in the one-stage group was converted to open cholecystectomy due to small bowel dilatation

Table 1 Baseline characteristics of 52 patients in the study

Baseline variables	One-stage	Sequential	p-value
Number of cases	14	38	-
Age in years: mean (s.d.)	56.4 (11.2)	57 (16.1)	0.89*
Sex (M:F)	7:7	11:27	0.16†
Proportion of abnormal LFT (%)	12/14 (86)	35/38 (92)	0.60#
Proportion of pre-op. pancreatitis (%)	2/14 (14)	7/38 (18)	0.73†
Stones seen on ERCP (%)	5/14 (36)	11/38 (29)	0.64†
Associated medical diseases (%)	5/14 (36)	9/38 (24)	0.39†

**unpaired t-test, equal variance; †chi-square test for 2 x 2 table; #Fisher's exact test; op.=operative*

Table 2 Outcomes of the study

Outcome variables	One-stage	Sequential	p-value
Proportion of successes (%)	9/14 (64)	35/38 (92)	0.03*
Proportion of post-op. complications (%)	3/14 (21)	3/38 (8)	0.33*
Overall op. time (minutes): median (range)	155 (95-185)	137 (95-315)	0.52†
Length of hospital stay (days): median (range)	7 (4-35)	8.5 (4-34)	0.20†

**Fisher's exact test; †Wilcoxon's Rank-sum test; op. = operative*

(n = 1), severe adhesions (n = 3) and bleeding from the cystic artery (n = 1). Three patients in the sequential group who were converted to open cholecystectomy had severe adhesion (n = 2) and choledochoduodenal fistula (n = 1).

The postoperative complication rates were 8% (3/38) and 21% (3/14) in the sequential and one-stage groups respectively (p = 0.33). Complications included post-ERCP pancreatitis (n = 2) and cystic duct stump leakage (n=1) in the sequential group and atelectasis (n = 1), pneumonia (n = 1) and wound infection (n = 1) in the one stage group.

The median overall operative time was 137 minutes (range: 95 to 315 minutes) in the one-stage group and 155 minutes (range: 95 to 185 minutes) in the sequential group (p = 0.52). Median length of hospital stay was 8.5 days (range: 4 to 34 days) and 7 days (range: 4 to 35 days) in sequential and one-stage group respectively (p = 0.20). There were no operative deaths in both groups.

Discussion

The advent of laparoscopic cholecystectomy has reopened the debate on the optimal management of patients with CBD stones or suspected CBD stones undergoing cholecystectomy. The major reason for this is to extend the benefits of minimally invasive surgery to this group of patients.

The laparoscopic technique for CBD stones clearance is a popular minimally invasive method but generally requires laparoscopic skills that may not be readily available. Endoscopic bile duct stone clearance, in conjunction with LC, has been proposed, either before or after LC. In the past, some surgeons advocated preoperative ERCP routinely in all patients presenting for LC. However, most endoscopic cholangiograms were normal in these patients and the rate of induced pancreatitis (2.5%) approximated the rate of suspected CBD stones (3.5%) on ERCP.[1] Routine ERCP prior to LC has been largely abandoned. Findings used to help identify patients likely to have CBD stones included elevated liver enzymes, jaundice, pancreatitis and ultrasonographic evidence of bile duct stones and/or dilated CBD.[2,3]

Any single method for the identification of CBD stones has low sensitivity and varies in positive predictive value. Hawdart reported that the combined presence of jaundice, enlarged CBD on ultrasonography, abnormal liver function test and abnormal bilirubin had high positive predictive value (PPV) but the combined sensitivity was no more than 65%.[2] In

contrast, cholangiography had the highest sensitivity and PPV. However, preoperative ERCP revealed choledocholithiasis in only 54.2% of patients who had clinical and biochemical evidence of CBD stones.[1] In this study, we demonstrated and confirmed the diagnosis of CBD stones in only 24% of patients in the sequential group and 36% in the one-stage group. Bile duct stone clearance was achieved in all patients.

At Ramathibodi hospital, preoperative ERCP is performed in symptomatic gallstone patients who have clinical and/or biochemical and/or ultrasound evidence suggesting the presence of CBD stones. Most patients undergo ERCP and LC in a sequential fashion. Fourteen patients so far underwent one-stage ERCP and LC. There were studies that showed few technical problems or complications resulting from the presence of inflated bowels when LC was performed immediately after ERCP.[1] Benefits of the one-stage treatment include the reduction of the number of anesthetic sessions, reduced hospital stay and costs.

The aim of this study was to compare the results of treatment in term of success rate, postoperative complications, overall operative time and length of hospital stay between the one-stage ERCP and LC group and the sequential group. The baseline differences (in age, sex, abnormal liver function test, preoperative pancreatitis and associated medical diseases) between the two groups were not statistically significant (Table 1). The success rate in the one-stage group (64%) was significantly lower than in the sequential group (92%; $p = 0.03$). The failure of LC in the one-stage group that was attributable to ERCP was in only one patient (due to small bowel dilatation). The remaining failures were attributed to severe adhesion ($n = 3$) and bleeding from cystic artery ($n = 1$) and not directly due to ERCP. ERCP before LC in the one-stage group may have little effect on the subsequent performance of LC.

The postoperative complication rate of the one-stage group was higher than that of the sequential group (21% and 8%, respectively), though not significantly ($p = 0.33$). There were two respiratory complications and one wound infection in the one-stage group. In our opinion, these complications were not caused by difficulties in the performance of the procedures. Postoperative complications in the sequential group included post ERCP pancreatitis ($n = 2$) and cystic duct stump leakage ($n = 2$).

The median overall operative time in the one-stage group was longer than in the sequential group; 155 minutes vs. 137 minutes, respectively (not significantly different $p = 0.52$). One reason for this difference was that in the one stage group time was lost during the changing of the patient's position from left lateral decubitus to supine, and time was also needed to prepare the patient and equipment for LC following ERCP. In our opinion, this time difference was not clinically significant.

The median length of hospital stay was not significantly different between the two groups (7 days in one-stage group and 8.5 days in sequential group, $p = 0.20$). However, the median time interval between procedures in the sequential group was 15 days (1-84 days) during which valuable work time might have been lost. Available data in our hospital did not allow us to calculate the cost of each procedure accurately. However, the cost from the patient's perspective may be estimated by a rough calculation: the cost of ERCP was between 3,500 to 7,500 Baht, that of LC between 5,000 to 7,000 Baht and the anesthetic cost was between 500 to 1,000 Baht. With the addition of medication costs and other equipment costs, the overall cost to each patient for the one-stage procedure was 9,000 to 15,000 Baht. The only difference in cost between the two approaches was the payment for either one or two anesthetic sessions (500 to 1,000 Baht). However, indirect costs in terms of the risk of two anesthetic sessions, as well as the cost of work lost during the procedure interval (i.e. in the sequential procedure) must be kept in mind. Hence the actual cost difference between the one stage and sequential approaches may be considerable and, based on cost minimization, the one stage approach may be more favorable.

Conclusions

Single stage ERCP and LC may be performed with little technical difficulties. The higher failure rate of the one-stage procedure was mainly due to severe adhesions and not from hyper-inflated bowels. The overall operative time, postoperative complications and length of hospital stay were not statistically different between the one stage and the sequential procedures. The direct costs between the two approaches differ only in anesthetic costs but the risk of two anesthetic sessions and indirect costs should also be considered.

Such a cost analysis seemed to favor the one stage procedure. However, these findings require further confirmatory prospective randomized controlled studies with larger number of patients in each group.

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