

EVALUATION OF SINGLE-STAGE ENDOSCOPIC RETROGRADE CHOLANGIO- PANCREATOGRAPHY AND LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Objective: To compare between one-stage approach Endoscopic Retrograde Cholangio-pancreatography and Laparoscopic Cholecystectomy (ERCP with LC) in the same session, and the current sequential approach (ERCP then LC in separate sessions). **Study design:** A prospective comparative study. **Patients and Methods:** 172 patients with the mean age 42 ± 11.8 years presented with combined gall bladder stones and CBD stones, divided into two groups: Group I(80 patients) allowed for one-stage ERCP/LC, and group II(92 patients) allowed for sequential ERCP/LC (LC performed within 7 days after ERCP). **Results:** The overall success rate to clear the CBD stones and complete LC was 92.5% vs 90.2% respectively. Minor complications in the form of mild post-ERCP pancreatitis, accessory cystic duct leakage and wound infection were observed in five patients in each group in our study (6.25% vs 5.4%), and no deaths were recorded. The mean hospital stay in single-stage ERCP/LC group was 2.8 ± 1.6 (1-12) days, while it was 5.2 ± 1.9 (2-15) days in sequential ERCP/LC group. Single-stage ERCP/LC procedure was more economic than sequential ERCP/LC procedure. The total cost was 10500 ± 1325 Egyptian pounds and 12250 ± 1850 Egyptian pounds respectively. Also, the frequency of anesthetic sessions and anesthetic time exposure was lower in single-stage ERCP/LC group. **Conclusion:** Both single-stage ERCP/LC and sequential ERCP/LC were safe and effective in detecting and removing common bile duct stones. However, a single surgical procedure for combined gall bladder and common bile duct stones is feasible, cost-effective, and should be available for most patients.

INTRODUCTION

Cholecysto-choledocholithiasis; gall bladder stones and common bile duct stones (CBDSs), is a common challenge in clinical practice (Martin et al., 2006). Common bile duct (CBD) stones may present in 5% to 15% of patients attending for a cholecystectomy (Ko and Lee, 2002). CBD stones are often asymptomatic but may be associated with biliary colic or one of its dangerous complications, including obstructive jaundice, biliary

pancreatitis, cholecysto-intestinal fistula and suppurative cholangitis (Verbesey & Birkett, 2008 and Ding et al., 2013).

The preoperative evaluation for CBD stones should include a careful history, biochemical tests and abdominal ultrasonography. Other preoperative investigations and intraoperative cholangiography in patients with absence of jaundice, normal liver function tests, and ultrasonographic evidence of a normal biliary tree (CBD diameter <9 mm) should not be

considered as routine diagnostic tools (Sharma et al.,2012).

Before endoscopic and laparoscopic era, the standard treatment for patients suffering from gallstones and common bile duct stones (CBDS) was open cholecystectomy and common bile duct exploration (Bansal et al., 2010). Laparoscopic cholecystectomy (LC) has become the first choice for the treatment of cholecystolithiasis in the past two decades. With the advancement of laparoscopic and endoscopic techniques, several alternative treatments, such as endoscopic retrograde cholangiopancreatography and endoscopic sphincterotomy (ERCP + EST) either preoperative or postoperative and laparoscopic common bile duct exploration (LCBDE), have been developed to treat the CBD stones (Lu et al.,2012).

Endoscopic clearance of CBD stones combined with laparoscopic cholecystectomy (LC) is a good option for treatment of gall bladder stones associated with CBD stones. Early LC after endoscopic CBD stone extraction is currently considered an appropriate management option "sequential ERCP and LC" (Schiphorst et al.,2008 andZang et al., 2011).

Laparoscopic cholecystectomy and ERCP in the same anesthetic session may be done "one-stage ERCP and LC" (Cuschieri et al.,1999 and Enochsson et al.,2004). This technique may reduce the number of anesthetic sessions, the length of hospital stay, and costs. The expected problem of this approach is the post-ERCP bowel distention that might interfere with the LC operation leading to

more operative complications (Suvikapakornkul et al.,2005).

The objective of the present study was to compare between the current sequential approach (ERCP then LC in separate sessions) and one-stage approach (ERCP with LC in the same session).

PATIENTS AND METHODS

Study Design: Our study was a comparative study, carried on one hundred and seventy two patients divided into two groups according to the patient's choice (the patient chose one session or two separate sessions): Group I(80 patients) was allowed for one-stage ERCP/LC, and group II(92 patients) was allowed for sequential ERCP/LC (LC performed within 7days after ERCP).

Patient Population: One hundred and seventy two patients with the mean age of 42 ± 11.8 (range 20-72) years presented with gall bladder stones and suspected CBD stones. All patients were attended to Surgical Department, Al-Azhar University Hospitals and referred from outpatient clinics in the period between March 2010 and March 2014. The study was approved by the local ethics committee of surgery department. Informed consent was obtained from all patients. The characters of patients included in both groups were specified in Table (1).

Exclusion criteria: (1) Patients including in American Society of Anesthesiologists (ASA) score > 3 (Tenconi et al., 2008). (2) Suppurative cholangitis (body temperature > 38.5 with rigor and right upper-quadrant abdominal pain and tenderness). (3) Acute pancreatitis (serum amylase 3 times higher than normal). (4) History of upper

abdominal surgery. (5) Decompensated liver disease. (6) Bleeding tendency.

Gall bladder stones were documented by ultrasound in all patients. CBD stones were suspected if the patients have jaundice or acute pancreatitis on

admission, previous episodes of jaundice or pancreatitis, elevated serum bilirubin and evidence of bile duct stones or dilated CBD on ultrasonogram (ultrasonographic CBD size greater than 10 mm).

Table (1): Characteristics of patients including in the study.

Parameters \ Groups	Group I	Group II	Total
Sample size	80	92	172
Age (years)	40 ± 9.4 (20-68)	44 ± 10.7 (22-72)	42 ± 11.8 (20-72)
Sex: M/F	23/57	33/59	56/116
Abdominal pain	71 (88.7%)	83 (90.2%)	154 (89.5%)
Clinical pancreatitis	7 (8.7%)	11 (11.9%)	18 (10.4%)
Jaundice	55 (68.7%)	60 (65.2%)	115 (66.8%)
Elevated bilirubin level	68 (85%)	77 (83.6%)	145 (84.3%)
Elevated alkaline phosphatase level	73 (91.2%)	85 (92.3%)	158 (91.8%)
Elevated liver enzymes	59 (73.7%)	71 (77.1%)	130 (75.5%)
Elevated amylase level	16 (20%)	17 (18.4%)	33 (19.1%)
Dilated bile ducts	61 (76.2%)	67 (72.8%)	128 (74.4%)
CBD stone by ultrasound	42 (52.5%)	51 (55.4%)	93 (54%)
Associated medical disorder	21 (26.2%)	25 (27.1%)	46 (26.7%)

Study procedures: In group I, ERCP was done under general anesthesia while the patient in a prone position. After cannulation and cholangiogram, if there were a CBD stones, sphinctrotomy was performed and the stones were removed by Dormia basket or balloon extractor. Stones larger than 10 mm were removed using a mechanical lithotripsy. Following ERCP, small-bowel gas was aspirated endoscopically as much as possible to

facilitate LC. The patients were then placed in the reverse Trendelenburg position. LC was performed using the standard four trocar technique. A sub-hepatic drain was placed.

In group II, ERCP was performed, then standard LC was done within one week in the same admission or in another one

During and after the ERCP and LC, all difficulties and complications were

recorded. Also, the operative time, success rate (non-conversion rate) and length of hospital stay were evaluated. Success rate mean successful LC after ERCP.

In all cases, patients underwent open surgery and CBD exploration if endoscopic stone removal failed or LC was difficult.

Statistical Analysis: Were performed by using statistical software SPSS (statistical program for social science). Categorical variables were compared by using the Chi-square test. When two variables were dichotomous, the Fisher exact test was used. To evaluate continuous variables, the student t test was used. Statistical significance was defined as a p value < 0.05.

RESULTS

One hundred and seventy two patients, their mean age were 42 ± 11.8 (range 20-72) years were divided into two groups; group I (mean age 40 ± 9.4 , range 20-68 years) and group II (mean age 44 ± 10.7 , range 22-72 years). There was no statistical significant difference between the two groups as regard the preoperative characteristics of patients (age, sex, clinical presentation, laboratory and radiological findings).

Outcomes of group I: success rate of ERCP to clear the CBD stones observed in 77/80 patients (96.25%). Laparoscopic cholecystectomy was completed in 74 patients (96.1%). six patients converted to open surgery 6/80 (7.5%), three patient due to failure of cannulation during ERCP (3.7%), two patients due to severe gastrointestinal distention (2.5%) and one

patient due to severe adhesion (1.25%) during LC, so the overall success rate in group I was 74/80 patients (96.1%). The mean endoscopic and laparoscopic time was 97.6 ± 12.3 (70.8-178.6) minutes. The period of hospital stay was 2.8 ± 1.6 (1-12) days. The postoperative complications recorded were 5/80 patients (6.25%), mild post-ERCP pancreatitis in two patients 2/5 (2.5%), cystic duct stump leakage in one patient 1/5 (1.25%) and wound infection in two patients 2/5 (2.5%). The professional fees was about 10500 ± 1325 Egyptian pounds (Table 2).

Outcomes of group II: success rate of ERCP was 87/92 patients (94.5%). Laparoscopic cholecystectomy was completed in 83 patients (90.2%). Conversion occurred in nine patients 9/92 (9.7%), five patients due to failure of cannulation during ERCP 5/92 (5.4%), three patients due to severe adhesion 3/92 (3.2%) and one patient due to bleeding cystic artery 1/92 (1.08%) during LC. So, the overall success rate in group II was 83/92 patients (90.2%). The mean endoscopic and laparoscopic time was 112 ± 13.7 (80-197) minutes. The period of hospital stay was 5.2 ± 1.9 (2-15) days. The rate of postoperative complications was 5/92 patients (5.4%), mild post-ERCP pancreatitis in one patient 1/5 (1.08%), bleeding cystic artery in one patient 1/5 (1.08%), accessory cystic duct leakage in one patient 1/5 (1.08%) and wound infection in two patients 2/5 (2.1%). The professional fees were about 12250 ± 1850 Egyptian pounds (Table 2).

Table (2): Outcomes of the two groups.

Parameters	Group I (No 80)	Group II (No 92)
Overall success	74 (92.5%)	83 (90.2%)
ERCP success	77 (96.25%)	87 (94.5%)
LC success	74/77 (96.1%)	83/87 (95.4%)
Rate of conversion to open surgery:	6 (7.5%)	9 (9.7%)
Failure of cannulation (ERCP)	3(3.7%)	5(5.4%)
Severe adhesion (LC)	1 (1.25%)	3(3.2%)
Severe gastrointestinal distention (LC)	2 (2.5%)	-
Bleeding cystic artery (LC)	-	1 (1.08%)
Mean endoscopic and laparoscopic time (min)	97.6 ± 12.3 (70.8-178.6)	112 ± 13.7 (80-197)
The period of hospital stay (day)	2.8 ± 1.6 (1-12)	5.2 ± 1.9 (2-15)
The rate of postoperative complications:	5 (6.25%)	5 (5.4%)
Post-ERCP pancreatitis	2 (2.5%)	1 (1.08%)
Cystic duct stump leakage	1 (1.25%)	-
Bleeding cystic artery	-	1 (1.08%)
Accessory cystic duct leakage	-	1 (1.08%)
Wound infection	2 (2.5%)	2 (2.1%)
Professional fees (Egyptian pounds)	10500 ± 1325	12250 ± 1850

DISCUSSION

LC is considered the first choice for treatment of calcular cholecystitis, but there is no concept on the ideal management of combined gall bladder stones and CBD stones. In last decades, multiple studies have compared different therapeutic techniques: sequential ERCP and LC versus single-stage laparoscopy "LC and laparoscopic CBD exploration" (Cuschieri et al., 1999), postoperative ERCP versus laparoscopic choledochotomy (Paul et al.,1992), and preoperative versus postoperative ERCP (Nathanson et al., 2005).

Laparoscopic exploration of CBD has been developed over the past 2 decades to extract common bile duct stones discove-

red incidentally during the course of LC (Millat et al.,1997andHong et al., 2006). It is a popular minimally invasive method but generally requires laparoscopic skills that may not be already available, Suvikapakornkul, et al. (2005). Paganini and Lezoche (1998), in a study on 284 patients undergoing laparoscopic exploration of CBD, reported an overall success rate of 94.6% was reported

Endoscopic retrograde cholangiopancreatography has been available in most major medical centers around the world for nearly 30 years (Rogers et al., 2010). ERCP still appears as an important method of treating CBD stones (Chang et al.,2000). Preoperative ERCP followed by LC seems to be the most frequently applied strategy but requires two periods

of anesthesia, occasionally two hospital admissions, which may increase the length of hospital stay and hospitalization expenses. Furthermore, if patients still have CBD stones detected by intraoperative cholangiography in LC after ERCP, surgeons will face the dilemma of depending on laparoscopic exploration of CBD, postoperative ERCP or traditional open surgery (Morino et al., 2006). Therefore, if LC and ERCP are performed at the same time, therapeutic strategy may become optimized (Iodice et al., 2001 and Tricarico et al., 2002).

In our study, ERCP and LC were performed by the same surgical team at the same time to demonstrate if the single-stage ERCP/LC is superior to sequential ERCP/LC in the management of combined gall bladder stones and CBD stones in terms of anesthetic hazards (single anesthetic exposure), length of hospital stay, and costs.

The overall success rate to clear the CBD stones and complete LC was statistically insignificant between the two study groups (92.5% vs 90.2%). The same findings were obtained by Morino et al. (2006) and Zang et al. (2013).

The rate of conversion (failure rate) was 7.5% for single-stage ERCP/LC group and 9.7% for sequential ERCP/LC group. It was due to failure of cannulation during ERCP, severe gastrointestinal distention, severe adhesion or intraoperative complications during LC. Suvikapakornkul et al. (2005) reported 5/14 patients (35.7%) in the one-stage group was converted to open cholecystectomy, and 3/38 patients (7.8%) in sequential group. Zang et al. (2013), in their study, recorded conversion rate of

2/91 patients (2.1%) vs 3/65 patients (4.6%). The results obtained by Mater (2006) was 5/200 (2.5%) vs 6/200 (3%).

The mean endoscopic and laparoscopic time in the present study was 97.6 ± 12.3 minutes for single-stage ERCP/LC group and 112 ± 13.7 minutes for sequential ERCP/LC group. The overall time reported in the study performed by Zang et al. (2013) was shorter (88.5 vs 88.1 minutes), but it was 112.1 ± 30.8 vs 104.9 ± 18.2 minutes in the study obtained by Ding et al. (2013).

The safety of the combination of endoscopic and laparoscopic techniques during the same session is a very important parameter for surgeons. Nowadays, morbidity and mortality in endoscopic and laparoscopic procedures are very low with skilled operators. The morbidity in the form of minor complications were observed in five patients in each group in our study (6.25% vs 5.4%) and no deaths were recorded. So, the two procedures were safe. These results agreed with most other studies, (La Greca et al., 2010 and Zang et al., 2013).

Mean hospital stay, cost effectiveness and rate of anesthetic exposure were the most important parameters in our study. We found that the mean hospital stay in single-stage ERCP/LC group was 2.8 ± 1.6 (1-12) days, while it was 5.2 ± 1.9 (2-15) days sequential ERCP/LC group. The mean hospital stay was significantly lower in single-stage ERCP/LC group than in sequential ERCP/LC group. Single-stage ERCP/LC procedure was more economic in the present study than sequential ERCP/LC procedure. The total cost was 10500 ± 1325 Egyptian pounds and 12250 ± 1850 Egyptian pounds respectively.

Also, the frequency of anesthetic sessions and anesthetic time exposure was lower in single-stage ERCP/LC group.

Morino et al (2006) reported that the hospital stay significantly reduced in single-stage technique (4.3 vs. 8 days) and consequently the total cost also significantly reduced (2.829 vs. 3.834 Euro). A non-randomized trial from Belgium performed by Topal et al.(2010) reported also that total hospital costs were significantly less after one-stage management (2636 vs. 4608 Euro in the two-stage).

Suvikapakornkul et al. (2005), in a study done in Thailand, reported that median length of hospital stay was 7 days and 8.5 days in one-stage and sequential group respectively. The cost 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. 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.

Another series performed in Saudi Arabia by Mater (2006) showed that the mean length of hospital stay for single-stage ERCP/LC was 2.1 days compared to 9.3 days in sequential ERCP/LC. Longer stay in hospitals lead to increased cost of health services and could lead to increased incidence of hospital acquired infections. The total cost for single-stage ERCP/LC

was 14376(3833.4 \$) vs 17349(4626.6 \$) Saudi Arabian Riyals for sequential ERCP/LC.

CONCLUSION

Both single-stage ERCP/LC and sequential ERCP/LC were safe and effective in detecting and removing common bile duct stones and were equal in patient acceptance. However, the duration of hospitalization was shorter for single-stage ERCP/LC. The overall cost was higher in sequential ERCP/LC. Therefore, a single surgical procedure for combined gall bladder and common bile duct stones feasible, cost-effective, and should be available for most patients.

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سامح جبر عطية - منصور محمد عبد الخالق

قسم الجراحة العامة - كلية الطب - جامعة الأزهر - القاهرة

الهدف من البحث: مقارنة بين عمل منظار القنوات المرارية - البنكرياسية المرتجع واستئصال الحويصلة المرارية بالمنظار الجراحي فى الجلسة نفسها من جهة وبين النهج الحالى وهو عمل منظار القنوات المرارية - البنكرياسية المرتجع ثم استئصال الحويصلة المرارية بالمنظار الجراحي فى جلسات منفصلة .

تصميم الدراسة: وقد تم ذلك عن طريق دراسة مقارنة مستقبلية .

المرضى والطرق: أجريت هذه الدراسة على 172 مريضاً، معدل أعمارهم 42 ± 11.8 عام، كانوا جميعاً يعانون من وجود حصوات بالقنوات المرارية مصاحبة لحصوات بالحويصلة المرارية، حيث قسموا إلى مجموعتين: المجموعة الأولى تشمل 80 مريضاً، حيث تم عمل المنظار المرارى والمنظار الجراحي فى نفس الوقت. المجموعة الثانية تشمل 92 مريضاً، حيث تم عمل المنظار المرارى أولاً ثم بعد ذلك وفى خلال 7 أيام تم عمل المنظار الجراحي.

النتائج: أظهرت النتائج أن معدل النجاح فى المجموعة الأولى كان 92.5% بينما كان فى المجموعة الثانية 90.2% على الرغم من حدوث بعض المضاعفات البسيطة فى المجموعتين مثل التهاب بسيط فى البنكرياس بعد منظار القنوات المرارية - البنكرياسية المرتجع، تسريب من القناة الخاصة بالحويصلة المرارية، والتهاب بالجرح وقد تم علاج هذه المضاعفات بسهولة، ولم يحدث أى وفيات بين المرضى. كما لوحظ أيضاً أن معدل بقاء المرضى بالمستشفى كان أقل فى المرضى المجموعة الأولى 2.8 ± 1.6 يوم بالمقارنة بمرضى المجموعة الثانية 5.2 ± 1.9 . اقتصادياً، كان معدل التكلفة الكلية لمرضى المجموعة الثانية أكثر منه لمرضى المجموعة الأولى 12250 ± 1850 ، 10500 ± 1325 جنية مصرى على التوالى. وأيضاً لوحظ أن معدل تعرض المرضى لمضاعفات التخدير كان أقل فى المرضى المجموعة الأولى.

الاستنتاج: خرجنا من هذه الدراسة بان كلتا الطريقتين لعلاج حصوات القنوات المرارية المصاحبة لحصوات الحويصلة المرارية آمنة وناجحة فى استخراج الحصوات واستئصال الحويصلة المرارية، لكن طريقة إجراء المنظار المرارى والمنظار الجراحي معا فى نفس الوقت هى طريقة عملية، سهلة واقتصادية. لذلك ينصح بتعميمها فى المؤسسات الطبية.