Results of treatment of patients with gallstone disease and ductal calculi by single-stage laparoscopic cholecystectomy and bile duct exploration

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Abstract

Introduction: Choledocholithiasis is the most common cause of obstructive jaundice. Common bile duct stones are observed in 10–14% of patients diagnosed with gall bladder stones. In the case of gall bladder and common bile duct stones the procedure involves not only performing cholecystectomy but also removing the stones from bile ducts.

Aim: To compare the results of the treatment of patients with gallstone disease and ductal calculi by one-stage laparoscopic cholecystectomy and common bile duct exploration with two other methods: one-stage open cholecystectomy and common bile duct exploration, and a two-stage procedure involving endoscopic retrograde cholan-aiopancreatography (ERCP) followed by laparoscopic cholecystectomy.

Material and methods: Between 2004 and 2011 three groups of 100 patients were treated for obstructive jaundice caused by choledocholithiasis. The first group of 42 patients underwent ERCP followed by laparoscopic cholecystectomy. The second group of 23 patients underwent open cholecystectomy and common bile duct exploration, whereas the third group of 35 patients underwent laparoscopic cholecystectomy with common bile duct exploration. The data were analysed prospectively. The methods were compared according to complete execution, bile duct clearance and complication rate. Complications were analysed according to Clavien's Classification of Surgical Complications. The results were compared using the ANOVA statistical test and Student's t-test in Statistica. Value of p was calculated statistically. A p-value less than 0.05 (p < 0.05) signified that groups differed statistically, whereas a p-value more than 0.05 (p > 0.05) suggested no statistically significant differences between the groups.

Results: The procedure could not be performed in 11.9% of patients in the first group and in 14.3% of patients in the third group. Residual stones were found in 13.5% of the patients in the first group, in 4.3% of the patients in the second group and in 6.7% of the patients in the third group. According to Clavien's classification of complications grade II and III, we can assign the range in the first group at 21.6% for grade II and 0% for grade III, in the second group at 21.4% and 3.6% and in the third group at 6.7% and 3.3% respectively.

Conclusions: The use of all three methods of treatment gives similar results. One-stage laparoscopic cholecystectomy with common bile duct exploration is after all the least invasive, safer and more effective procedure.

Key words: common bile duct stones, laparoscopic exploration of the common bile duct, choledochotomy.

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Introduction

About 10-14% of patients with cholelithiasis require an additional treatment due to choledocholithiasis. Since the 1990s laparoscopic cholecystectomy has been the most commonly performed procedure for the treatment of gallstone disease. Although the treatment of common bile duct stones has changed during the last decade it still seems to be controversial. Currently there are three methods of treatment for choledocholithiasis. The first method is one-stage open cholecystectomy with common bile duct exploration. The second one is a two-stage procedure of endoscopic retrograde cholangiopancreatography (ERCP) followed by laparoscopic cholecystectomy. The third way is one-stage laparoscopic cholecystectomy with common bile duct exploration [1-23]. At the time of the dynamic development of minimally invasive techniques, open common bile duct exploration is sidelined for cases where the other techniques are ineffective or unavailable. The most commonly used procedure is the two-stage approach that includes ERCP and endoscopic sphincterotomy, before, during or after laparoscopic cholecystectomy. The two-stage approach is at risk of complications of both procedures - ERCP and laparoscopic cholecystectomy [2, 4, 9]. The third type of procedure is used rarely due to technical difficulties facing the surgeon performing common bile duct (CBD) exploration and removing stones with a Dormia basket or choledochoscope.

Aim

The aim of this study is to compare the results of the treatment of patients with gallstone disease and ductal calculi by one-stage laparoscopic cholecystectomy and common bile duct exploration with two other methods: one-stage open cholecystectomy and common bile duct exploration, and a two-stage procedure involving ERCP followed by laparoscopic cholecystectomy.

Material and methods

This prospective study involved the analysis of treatment of 100 patients for gallstone disease and bile duct calculi in the years 2004–2011. The inclusion criteria were: obstructive jaundice, ASA grade I–III and patient's consent to undergo the proposed therapeutic procedure. Obstructive jaundice was diag-

nosed on basis of: symptoms (pain in the right upper part of the abdomen), physical examination (yellow skin and eyes, brown urine, pale stool), serum liver biochemical tests (total bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), γ -glutamyl transpeptidase (GGTP), alkaline phosphatase (ALP)), and transabdominal ultrasound (US) (examination of the right upper quadrant: gallbladder, bile ducts). The increased level of serum liver biochemical tests, stones in gallbladder and dilatation of common bile duct greater than 6 mm were detected in all 100 patients. Moderate increase of total bilirubin level (1.3-1.79 mg/dl) was reported in 12 patients; these patients were included in the study due to US findings that confirmed the lack of CBD stones. Exclusion criteria were: acute pancreatitis, cholangitis, ASA grade IV-V. The study was divided into three periods (years 2004–2006, 2007–2008 and 2009-2011). All patients underwent the same therapeutic procedure at the proper period of the study. The first group of patients underwent ERCP followed by laparoscopic cholecystectomy in the years 2007-2008. The second group of patients underwent open cholecystectomy with common bile duct exploration in the years 2004-2006, and the third group underwent laparoscopic cholecystectomy with common bile duct exploration in 2009-2011. If a patient did not consent to the proposed treatment at the proper period of study, he was excluded from the study and underwent one of the other two methods of treatment.

Laparoscopy was performed using the 10 mm 0° angled laparoscope, the Olympus set. Intra-abdominal pressure of carbon dioxide was maintained in the range of 12–15 mmHg. Cholangiography was performed using the C-arm fluoroscope MCA-C-6200, ERCP was performed using the Fujinon ED-250XT8/B duodenoscope, and choledochoscopy was performed using the Karl Storz 3.6-Fr choledochoscope.

The technique of endoscopic retrograde cholangiopancreatography and laparoscopic cholecystectomy

Patients were laid on the left side with a slightly raised upper half of the body. Light sedation and analgesia (midazolam, butylscopolamine, ketoprofen) were given. The duodenoscope was introduced into the descending duodenum. After visualisation of the papilla of Vater, a catheter was introduced into

the CBD and contrast was injected into the biliary ducts. If necessary, papillotomy (cutting the ampulla of Vater) or sphincterotomy was done. Bile duct stones were removed using a Dormia basket or Fogarty catheter. If CBD clearance failed, a prosthesis (rigid or Pig-tail, 4-9 Fr) was introduced into the CBD. A laparoscopic cholecystectomy was performed 2-4 weeks after ERCP. The operation was performed under general anaesthesia in the reverse Trendelenburg position. Four-trocar (A, B, C, D) technique was used (the placement of trocars is described in laparoscopic CBD exploration technique). When the cystic duct was dissected, it was ligated with a clip near the gallbladder neck and incised below the clip transversely or longitudinally. Then a catheter (ureteral Couvelaire Balton or vascular Fogarty Hagmed, 4-5 Fr) was introduced into the CBD and the distal part of the cystic duct was delicately ligated with a clip or closed using atraumatic forceps. About 20 ml of diluted contrast (10 ml of 350 Iomerson Bracco and 10 ml of 0.9% NaCl) was injected into the biliary tree and dynamic cholangiogram was performed using a C-arm. If the biliary ducts were clear, the cystic duct was ligated with clips below the incision and divided. The gall bladder artery was also ligated with clips and divided, and the gall bladder was excised and removed. A silicone drain (12-16 Fr) was placed into the operated area for 24 h.

The technique of open cholecystectomy with common bile duct exploration

Patients were operated on under general anaesthesia, in the back position with a slight bend of the right costal margin. The incision was made below and parallel to the right costal margin (Kocher incision). When Calot's triangle was dissected, the cystic artery was closed with absorbable suture and divided, and the cystic duct was closed with absorbable suture below the gallbladder neck. Then the CBD was dissected, the Kocher manoeuvre was performed and two stay sutures (Vicryl 3-0) were placed near the planned incision of the CBD. The anterior surface of the CBD was incised for 5-7 mm at the midpoint of the CBD. The cholangioscope was introduced through the incision to visualize the hepatic ducts and CBD. Calculi were removed using forceps, Dormia basket, Fogarty catheter, manually squeezing from the duct, flushing with saline. If necessary, the incision was extended to 1015 mm. A check choledoscopy was performed twice at the end of the procedure to ensure complete clearance of the biliary system. Clearance of the distal CBD was considered complete only when the choledochoscope was negotiated into the duodenum through the ampulla of Vater. The CBD was closed over a T-tube (Medical latex drain, Ch 10-16) using interrupted absorbable sutures (Vicryl 3-0). The posterior surface of a short arm of the T-tube was excised and a V-shape incision in the front of a long arm was made before the T-tube was placed in the CBD. Then a control cholangiography was performed through the T-tube and the gallbladder was excised and removed. The operating area was drained gravitationally using a silicone drain, diameter 16–24 Fr.

The technique of laparoscopic cholecystectomy with common bile duct exploration

Patients were operated on under general anaesthesia in a reverse Trendelenburg position. The first 10 mm trocar (A) was introduced by minilaparotomy below the umbilicus for insufflation of carbon dioxide and for a 0° angled laparoscope. Other trocars were placed under direct vision: the second 10 mm trocar (B) was introduced in the epigastric region, the third 5 mm trocar (C) in the right axillary line, 3-4 cm above the anterior iliac spine, the fourth 5 mm trocar (D) in the midclavicular line, 2-3 cm above the umbilicus, and the last fifth 5 mm trocar (E) below the costal margin, 1-3 cm medial to the midclavicular line. Trocar D was used for cholangioscopy of hepatic ducts and trocar E for cholangioscopy of CBD. In 2009-2010, all patients underwent transcholedochal exploration, and in 2011 we began to carry out transcystic exploration. The transcystic approach was used if the cystic duct was enlightened and dilated (> 3 mm), the CBD was slightly dilated (7–9 mm), stones were smaller than the lumen of the cystic duct, not multiple (< 5) and located only in the CBD. If transcystic choledochoscopy of hepatic ducts failed, transcystic cholangiography was carried out to detect stones in hepatic ducts. If transcystic extraction of CBD stones failed or stones occurred in hepatic ducts, the transcholedochal approach was applied. The CBD exploration was performed with an incision of a distal part of the common hepatic duct just before the junction with the cystic duct. The longitudinal incision of total length 6-7 mm was start-

ed on the anterior surface of the common hepatic duct (2-3 mm) towards the CBD (4-5 mm) using the laparoscopic L-shape hook. If necessary, the incision was extended to 10-15 mm. Choledochoscopy was performed using a flexible choledochoscope. Stones were extracted with a Dormia basket, Fogarty catheter, atraumatic forceps, pushed into the duodenum, flushed with saline or milking technique was used. Single 2–8 mm stones were removed from the abdominal cavity with forceps through trocar B. Large (> 8 mm) and multiple stones were placed in a bag made of latex glove and removed through trocar A. After all stones were extracted, a check cholangioscopy of hepatic ducts and CBD was performed twice to ensure clearance of the biliary system. Clearance of the distal CBD was considered only when the choledochoscope was negotiated into the duodenum through the ampulla of Vater. After the transcystic exploration was performed, the cystic duct was ligated with clips or absorbable suture. There were two types of CBD closure after choledochotomy: primary closure or T-tube drainage. Primary closure with continuous absorbable suture (Vicryl 3-0) was used if stones were small (< 5 mm) and single (< 4-6 mm), and there was no inflammation or damage in the CBD, especially in the papilla of Vater. In other cases, T-tube drainage was used. Then cholecystectomy was performed. The operated area was drained with a silicone 16-24 Fr drain for 24-48 h or until bile leak stopped. In case of T-tube drainage a check cholangiography was performed on postoperative day 4–7. If there was no evidence of residual stones, the T-tube was closed and the patient was discharged on the next day. The T-tube was removed after 2–3 weeks. In case of residual stones, the T-tube was left and patients underwent ERCP. Patients with primary closure or transcystic exploration of the CBD were discharged on postoperative day 3-4.

The incidence of postoperative complications were analysed, such as: wound infection, intra- and postoperative bleeding, bile leak (near the T-tube, within the drain or through the wound), residual stones, acute pancreatitis, pneumonia, and other complications (cardiac, nephrological, etc.). Complications were stratified using a validation system developed by Clavien. This system stratifies complications into five grades ranging from any deviation from the normal postoperative course (Grade I), those requiring certain pharmacological interventions, blood transfusions, parenteral nutrition,

wound infection requiring antibiotics (Grade II), those requiring surgical, endoscopic or radiologic intervention (Grade III), life-threatening complications (Grade IV), to death (Grade V) [13]. The duration of procedures and postoperative hospital stay were also analysed. Conversion to an open operation and failure of ERCP were considered as failure of the employed method of treatment. Residual stones were defined as failure to clear the bile duct of stones in the employed procedure requiring subsequent intervention. Residual stones were detected as during, as after the procedure. If ERCP failed, a biliary prosthesis was introduced to achieve bile duct clearance. In all cases of the first group in the time of laparoscopic cholecystectomy a transcystic cholangiography was performed to detect residual stones. If laparoscopic CBD exploration failed to achieve bile duct clearance the T-tube drainage was used followed postoperative ERCP. A T-tube cholangiogram was performed on postoperative day 4-7 to check bile duct clearance in cases of T-tube drainage in the second group. In all other cases no additional examination was done. If clinical symptoms of residual stones appeared (pain, yellow skin, pale tool, dark urine, increased level of biochemical liver tests) then magnetic resonance cholangiography was performed. The exact characteristics of the patients from studied groups are presented in Table I.

The groups did not differ in mean age (p = 0.184), sex (p = 0.186), ASA (p = 0.707), CBD diameter (p = 0.299), total bilirubin level (p = 0.086), ALT (p = 0.839), AST (p = 0.292), GGTP (p = 0.336), or ALP (p = 0.401).

Results

Methods of common bile duct exploration are presented in Table II. In most cases, choledochotomy was performed for CBD exploration. In most cases T-tube drainage was used. Only Clavien grades I, II and III were observed (Table III).

In most cases, the postoperative course was normal (Clavien grade I). The most common Clavien grade II complication in the first group was pancreatitis (7 patients), and in one case pneumonia was diagnosed. In the second group the most common Clavien Grade II complication was an infection of the wound (5 patients); however, in one case cardiac arrhythmia (atrial fibrillation) was diagnosed. There were two Clavien grade II complications in the

Table I. Characteristic of patients from studied groups

Parameter	ERCP + laparoscopic cholecystectomy	Open CBD exploration	Laparoscopic CBD exploration
Age, mean (range)	61.3 (27–93)	63.2 (31–88)	58.3 (23–81)
Sex, n (%)	F – 24 (57.1) M – 18 (42.9)	F – 15 (65.2) M – 8 (34.8)	F – 27 (77.1) M – 8 (22.9)
ASA, n (%)	I – 7 (16.7) II – 21 (50) III – 14 (33.3)	I – 4 (17.4) II – 12 (52.2) III – 7 (30.4)	I – 9 (25.7) II – 15 (42.9) III – 11 (31.4)
Diameter of CBD, mean (range) [cm]	10.6 (7–18)	11.8 (9–25)	11.1 (8–18)
Total bilirubin, mean (range) [mg/dl]	3.8 (1.3–9.13)	5.5 (1.98–15.26)	5.8 (1.49–22.23)
ALT, mean (range) [U/I]	300.0 (32–985)	315.0 (50–635)	269.7 (16–821)
AST, mean (range) [U/l]	170.8 (14–452)	201.1 (34–485)	219.3 (26–504)
GGTP, mean (range) [U/I]	529.5 (26–1655)	387.7 (111–1306)	366.1 (96–1681)
ALP, mean (range) [U/I]	207.0 (72–839)	248.2 (138–681)	247.4 (66–652)

Table II. Methods of common bile duct exploration

Method of CBD exploration	Open CBD exploration, n (%)	Laparoscopic CBD exploration, n (%)
Choledochotomy	23 (100%)	27 (90%)
Transcystic approach		3 (10%)
Primary closure of CBD	2 (8.7%)	4 (13.3%)
T-tube drainage	21 (91.3%)	26 (86.7%)

Table III. Clavien's classification of complications

Clavien's grade	ERCP + laparoscopic cholecystectomy, n (%)	Open CBD exploration, n (%)	Laparoscopic CBD exploration, <i>n</i> (%)
I	29 (78.4%)	21 (75%)	27 (90%)
II	8 (21.6%)	6 (21.4%)	2 (6.7%)
III	=	1 (3.6%)	1 (3.3%)
IV	_	_	_
V	=	=	_

third group: controlled intra-abdominal bleeding requiring transfusion of two units of blood; and the second complication – pulmonary embolus diagnosed in computed tomography (CT) scan and successfully treated pharmacologically. There were no Clavien grade III complications in the first group. In the second group, there was one Clavien grade III complication (3.6%): bleeding duodenal ulcer was

injected with adrenaline solution using endoscopy; two units of blood were transfused. There was one Clavien grade III complication (3.3%) in the third group, namely intra-abdominal bleeding requiring reoperation; the bleeding CBD vein was ligated and 6 units of blood were transfused. There were no Clavien grade IV and V complications in any of the 3 groups of patients. No statistically significant dif-

Table IV. Incidence of complications in studied groups

Complications	ERCP + laparoscopic cholecystectomy, n (%)	Open CBD exploration, n (%)	Laparoscopic CBD exploration, n (%)
Residual stones	5 (13.5%)	1 (3.6%)	2 (6.7%)
Controlled bile leak	0	2 (8.7%) < 2 days	2 (6.7%) < 2 days
		0 (0%) > 2 days	1 (3.3%) > 2 days
Pancreatitis	7 (24.1%)	-	_
Pneumonia	1 (2.7%)	-	_
Wound infection	_	5 (17.9%)	_
Arrhythmias	-	1 (3.6%)	-
Pulmonary embolism	_	_	1 (3.3%)
Controlled postoperative intra-abdominal bleeding	-	-	1 (3.3%)
Postoperative intra-abdominal bleeding requiring reoperation	-	-	1 (3.3%)
Bleeding duodenal ulcer	_	1 (3.6%)	_

ferences in complications were discovered in compared groups of patients (p = 0.352).

Table IV shows the incidence of various complications in each group of patients. High incidence of post-ERCP pancreatitis (24.1%) and wound infection after open CBD exploration (17.9%) were noted. These complications did not occur in patients undergoing a laparoscopic procedure. Residual stones were managed with open (4) and laparoscopic (1) CBD exploration in the first group of patients. Patients with residual stones in the second and third groups underwent postoperative ERCP effectively. There was no need for surgical or endoscopic intervention to treat postoperative bile leak in the second and third group of patients. Prolonged hospital stay for 13 days was observed in only one case of bile leak in the third group.

Efficiency of procedures

Endoscopic retrograde cholangiopancreatography failed in 5 cases in the first group (11.9%). The reasons for failure were: a papilla of Vater located in the duodenal diverticulum (2), large impacted stone in the CBD (1), after gastric resections and gastro-jejunal anastomosis (2). Common bile duct exploration was performed successfully in all cases in the second group. The reasons for conversion in the third group were: inflammation of the hepa-

to-duodenal ligament enabled dissection of the CBD (2), failed extraction of impacted CBD stone (2), uncertain closure of the cystic duct (failed ligating and suturing) because of gangrenous cholecystitis (1).

The average duration of procedures is presented in Table V. The average duration of procedures differed statistically ($p=13\times10^{-7}$, or p<0.05). The influence of the learning curve is observed in the third group: average duration of the first ten operations was 180 min and the last one took about 140 min. In addition, the average duration of laparoscopic transcystic CBD exploration was even shorter and came down to 120 min.

Postoperative stay in studied groups is presented in Table VI. Postoperative stay differed statistically ($p=3.2\times10^{-12}$, or p<0.05). The longest postoperative stay was after open CBD exploration (10.6 days). However, there was no statistical difference in postoperative stay between the first and the third group; ERCP followed laparoscopic cholecystectomy and laparoscopic CBD exploration (p=0.592).

In addition, the effectiveness of procedures was analysed in regard to overall performance of the procedure and achieved clearance of CBD stones (Table VII). The effectiveness of procedures was not statistically different between the studied groups (p = 0.806).

Table V. Average duration of procedures (in minutes)

ERCP + laparoscopic cholecystectomy		Open CBD exploration	Laparoscopic CBD	
ERCP	Laparoscopic cholecystectomy	-	exploration	
77.6 (20–110)	66.9 (40–100)			
	144.5 (75–175)	124.8 (60–235)	163.8 (115–235)	

Table VI. Postoperative stay in studied groups

Postoperative stay [days]	ERCP + laparoscopic cholecystectomy		Open CBD exploration	Laparoscopic CBD exploration
	3.2 (1–10)	2		
	ERCP	LC		
	5.2 (3-	-12)	10.6 (7–15)	7.1 (4–16)

Table VII. Effectiveness of procedures

	ERCP + laparoscopic cholecystectomy	Open CBD exploration	Laparoscopic CBD exploration
Overall performance of the procedure	88.1% (37/42)	100% (23)	85.7% (30/35)
Achieved clearance of CBD stones	86.5% (32/37)	95.7% (22/23)	93.3% (28/30)
Effectiveness of procedures	76.2% (32/42)	95.7% (22/23)	80% (28/35)

Discussion

One of the inclusion criteria in our study was obstructive jaundice diagnosed on the basis of increased level of serum liver biochemical tests (ALT, AST, GGTP, total bilirubin) and transabdominal ultrasound of the bile ducts. Liver biochemical tests have the most utility in excluding the presence of CBD stones. The American Society for Gastrointestinal Endoscopy (ASGE) reported normal liver biochemical test results in more than 97% of 1000 patients undergoing laparoscopic cholecystectomy [24]. The positive predictive value of any abnormal liver biochemical test result by ASGE was 15%; according to other authors it was 25-50% [24-26]. Liver biochemical tests increase progressively with the duration and severity of biliary obstruction. The mean total bilirubin level in a large group of patients with choledocholithiasis was reported at 1.5 mg/dl to 1.9 mg/dl, and only one third of these patients had a bilirubin level of 4 mg/dl or higher [24, 27, 28]. Transabdominal US has a relatively poor sensitivity (22% to 55%) for detecting CBD stones in comparison with methods such as conventional CT with 65% to 88% sensitivity, magnetic resonance cholangiogra-

phy (MRC) with sensitivity 85% to 92%, CT cholangiography with sensitivity 85% to 92%, and endoscopic ultrasound (EUS) with sensitivity 89% to 97% [24, 29, 30]. The sensitivity of transabdominal US increases significantly from 77% to 87% in detecting dilatation of CBD, and a finding is often associated with choledocholithiasis [24, 31-33]. The normal diameter of CBD is 3 mm to 6 mm. Common bile duct dilatation greater than 8 mm in a patient with stones in the gallbladder usually indicates biliary obstruction [24, 32]. Evaluating the criteria for inclusion in our study retrospectively, we can conclude that they are close to the ASGE guidelines in 2010. According to the ASGE, the predictors of choledocholithiasis are: very strong (CBD stone on transabdominal US, clinical ascending cholangitis, total bilirubin level > 4 mg/dl), strong (dilated CBD on transabdominal US > 6 mm with cholecystolithiasis, total bilirubin level 1.8-4 mg/dl) and moderate (abnormal liver biochemical test other than bilirubin, age greater than 55 years, clinical gallstone pancreatitis). Based on the manifestation of one or more predictors we can determine the probability of occurrence of choledocholithiasis as: high (manifestation of any very strong

predictor or presence of two strong predictors), low (no predictors present) and intermediate (all other patients). The ASGE recommends biochemical liver tests and ultrasound examination to determine the likelihood of choledocholithiasis [24]. In our study only patients with a high likelihood of choledocholithiasis according to guidelines established by the ASGE were included. Patients with a high risk of choledocholithiasis should undergo ERCP; laparoscopic CBD exploration may be performed, as an alternative to ERCP, which is recommended by ASGE. Magnetic resonance cholangiography and endoscopic ultrasound are recommended for diagnosis of residual stones [24]. In the studies of Tinoco et al. and Noble et al. the inclusion criteria for laparoscopic CBD exploration were the increased levels of total bilirubin, ALT, ALP and enlarged CBD diameter [1, 20]. In a multicentre randomized trial of the European Association for Endoscopic Surgery (EAES), patients were qualified for laparoscopic CBD revision or ERCP based on the results of biochemical liver tests and ultrasound of the gallbladder and bile ducts [2]. Currently, most patients with obstructive jaundice undergo a two-stage procedure: ERCP followed laparoscopic cholecystectomy. In some cases, it is not possible to perform ERCP, because of having undergone Billroth II gastrectomy, abnormally positioned papilla of Vater or located in the duodenal diverticulum and stenosis of the distal CBD. It was not possible to perform ERCP in 5 cases (11.9%) in our study. The combination of two methods is additionally at risk of complications from both the applied procedures. However, only two types of post-ERCP complications were observed in the first group of patients - 7 patients experienced mild acute pancreatitis and 1 patient experienced pneumonia. In our department, there were more serious complications after ERCP: severe acute pancreatitis, bleeding after endoscopic sphincterotomy or duodenal perforation requiring surgical intervention, post-ERCP cholecystitis or cholangitis. These patients were not included in this study because they did not meet the inclusion criteria. Andriulli et al. performed an analysis of prospective studies on complications of ERCP in the years 1997-2006 (21 studies, 16 855 cases in Medline). According to their study the prevalence of overall complications of ERCP is 6.85%, of which 1/4 are severe, acute pancreatitis rate is 3.47% (of which 11.4% are severe), infection (cholecystitis or cholangitis after ERCP) rate is 1.44%, bleeding rate is

1.34%, perforation rate is 0.6% and mortality rate is 0.33% [34]. According to other authors the prevalence of overall post-ERCP complications is 4–15.9%, whereas the acute pancreatitis rate is 1-7% [35]. According to the ASGE, the risk of acute pancreatitis after ERCP is 1.3-6.7%, risk of infection is 0.6-5.0%, bleeding risk is 0.3–2.0%, and the perforation risk is 1–1.1% [24]. In our study we did not evaluate the long-term complications after ERCP and endoscopic sphincterotomy, which occur quite often and were described by other authors (stricture of papilla of Vater causing impeded flow of bile, narrowing or increase light mouth of the bile duct to the duodenum, bile reflux and recurrent cholangitis) [3, 14]. Duodenal biliary reflux may be the cause of recurrent choledocholithiasis. Some authors have suggested an increased risk of carcinogenesis after endoscopic sphincterotomy and chronic cholangitis [14]. However, these reports have not been well documented. Because of these complications with endoscopic sphincterotomy it is not recommended for young adults. Complications of laparoscopic cholecystectomy are quite rare. We did not study Clavien complications of grade II-V after laparoscopic cholecystectomy in the groups. Nonetheless, there were several complications (Clavien grade II-V) at our department, such as intra-abdominal bleeding, wound infection, biliary fistula, and bile duct injury. The rate of these complications is quite low and comparable with data collected by other authors. For example, the rate of bile duct injury is about 1% at our department, and according to other authors 0.5–3.5%. The conversion rate of laparoscopic cholecystectomy (planned as well as emergency) is about 7% at our department, though in comparison with the data by Kopeć and Marciniak the conversion rate is 5.85% [23]. In our study the average duration of laparoscopic CBD exploration was the longest in comparison with other methods. It should be emphasised that the duration of the last ten laparoscopic CBD explorations fell to 140 min (vs. 144.5 min ERCP + laparoscopic cholecystectomy) due to mastering the technique of intracorporeal suturing and knotting as well as choledochoscopy. The average postoperative stay was 5.2 days in the first group of patients (3.2 days after ERCP + 2 days after laparoscopic cholecystectomy). Nonetheless, the postoperative stay is shorter in comparison with other groups (vs. 10.6 days in open and 7.1 days in laparoscopic CBD exploration groups), whereas the combination of

both procedures prolongs the total hospital stay. The laparoscopic cholecystectomy was usually performed 2-4 weeks after ERCP, so additional patient's admittance procedures were required (documentation, laboratory findings, examination, premedication, etc.) and total hospital stay was therefore prolonged. Intraoperative cholangiography was always performed in all patients undergoing laparoscopic cholecystectomy and there were no residual stones in any case. Reinders et al. compared early (< 72 h) and delayed (after 6-8 weeks) laparoscopic cholecystectomy after ERCP and found that the two groups did not differ in the rate of complications or conversions while the delayed group had an increased incidence of biliary colic, pancreatitis, and cholecystitis (36.2% vs. 0.5%) [36]. In cases where there were no complications in the third group (laparoscopic CBD exploration) the postoperative period was 4-5 days. Some authors reported recurrent CBD stones after ERCP, and some of them are observed intraoperatively during laparoscopic cholecystectomy. It is important to time when the laparoscopic cholecystectomy is performed after ERCP for the reason that the laparoscopic cholecystectomy is best performed 2-3 days after ERCP, if there were no complications. Bostanci et al. compared three groups of patients operated on at different times after ERCP (up to 2 days, 3-42 days and above 42 days) and found no difference between the groups in terms of conversion and complication [37]. The percentage of residual stones after ERCP ranges according to various authors from 9% (Campagnacci et al.) to 43% (Akhbar et al.) [7]. In our study, residual stones were detected during ERCP in 13.5% of patients in the first group, whereas post-ERCP residual stones were not found. Laparoscopic CBD exploration is an even safer (90% no postoperative complications) and more effective (6.7% residual stones) procedure. Safety confirms the absence of grade IV-V Clavien complications. The effectiveness was analysed based on the conversion rate and residual CBD stones. Other authors have also analysed the conversion rate and clearance of the common bile duct. Our data are similar to those of other authors. Noble et al. reported 84.5% Clavien grade I complications, 15.5% Clavien grade II–IV complications, 0.23% (1 mortal) Clavien grade V complication; the conversion rate was 8.3%, vs. 14.3% in our study, controlled bile leak was 15.6%, vs. 10% in our study, residual stones came to 1.8%, vs. 6.7% in our study. In the

study of Noble et al. there was a lower conversion rate and lower rate of residual stones in comparison with our study because of the greater number of patients (436), better technical equipment (laparoscopic ultrasound, electrohydraulic lithotripsy, two 3-5 mm choledochoscopes were used) [20]. In our study, the reason for the first two conversions was residual CBD stones. Now in such cases we continue laparoscopy and use T-tube drainage of the CBD and then we perform postoperative ERCP. As the study of Campagnacci et al. showed, in 63 laparoscopic CBD explorations residual stones were found in 1.6% (electrohydraulic lithotripsy was used), and the conversion rate was 1.6% [7]. By contrast, the study of Tinoco et al. found that in 481 laparoscopic CBD explorations residual stones were found in 1.5%, and the conversion rate was 1.45% (laparoscopic ultrasound and two 3-5 mm choledochoscopes were used) [1]. Choledochotomy was the preferred approach in most of our laparoscopic CBD explorations, while the transcystic approach was employed 3 times. The transcystic CBD exploration is limited due to the small diameter of the cystic duct, large or multiple stones, or stones located in the hepatic ducts. The sharp angle of the cystic duct-CBD junction makes it difficult to examine the hepatic duct using a choledochoscope. If choledochotomy was performed there were two methods of CBD closure: using T-tube drainage or primary closure. Primary closure was used if stones were small (< 5 mm) and single (< 4–6), there was no extensive manipulation inside the ducts and ampulla during extraction of stones, and the exploration was performed under the direct vision of a choledochoscope. We preferred using T-tube drainage in most procedures (86.7%) because of decompression of the biliary tree in case of residual stones or inflammation oedema. Another advantage of T-tube drainage was the possibility to perform postoperative cholangiography through the T-tube, and in the case of residual stones it was possible to extract them by the T-tube. In our study, one bile leakage after the primary CBD closure was observed, in the amount of 50-150 ml/day, without cholestasis. Bile leakage was transient until the ninth postoperative day; no auxiliary treatment was required. Some authors have reported complications of T-tube drainage, such as dislocation of the T-tube that causes biliary obstruction or bile leak, ascending cholangitis due to prolonged T-tube drainage, or biliary peritonitis after removal of the T-tube [38]. In our study, there were no such complications. According to the analysis of the Cochrane Database by Gurusamy *et al.* in 2007, the superiority of the use of T-tube drainage instead of primary closure of the CBD, and vice versa, was not shown [39].

Conclusions

Laparoscopic CBD exploration is a procedure with a significant learning curve, reflecting the requirement of mastering intracorporeal suturing and knotting as well as choledochoscopy. The results of treatment in terms of CBD stone clearance by this method are comparable with the results of open CBD exploration, and with a two-stage procedure of ERCP and laparoscopic cholecystectomy. Laparoscopic CBD exploration performed by an experienced surgeon is just as effective and safe in treatment of choledocholithiasis as the other 2 methods are. Endoscopic retrograde cholangiopancreatography is indicated for high-risk patients (ASA IV, V). If ERCP fails, an operation can be performed. Laparoscopic approaches have advantages as minimally invasive and single-stage procedures. The use of choledochoscopy during a single-stage operation reduces the incidence of post-ERCP complications, such as acute pancreatitis, duodenal biliary reflux, and papilla trauma, which is especially important for young adults. Despite slightly longer operative time, the benefits of laparoscopic CBD exploration are the same as after laparoscopic cholecystectomy: shorter hospital stay, lower incidence of infection and faster return to physical fitness.

References

- 1. Tinoco R, Tinoco A, El-Kadre L, et al. Laparoscopic common bile duct exploration. Ann Surgery 2008; 247: 674-9.
- Cuschieri A, Lezoche E, Morino M, et al. E.A.E.S. multicenter prospective randomized trial comparing two-stage vs. single-stage management of patients with gallstone disease and ductal calculi. Surg Endosc 1999; 13: 952-7.
- 3. Parra-Membrives P, Diaz-Gomez D, Vilegas-Portero R, et al. Appropriate management of common bile duct stones: a RAND Corporation/UCLA appropriateness method statistical analysis. Surg Endosc 2010; 24: 1187-94.
- Martin DJ, Vernon DR, Toouli J. Surgical versus endoscopic treatment of bile duct stones. Cochrane Database Syst Rev 2006; 2: CD003327.
- Ponsky LJ. Laparoscopic Biliary surgery: will we ever learn? Surg Endosc 2010; 24: 2367.

- Grubnik V, Tkachenko A, Vorotyntseva K. Comparative prospective randomized trial: laparoscopic versus open common bile duct exploration. Videosurgery Miniinv 2011; 6: 84-91.
- Campagnacci R, Baldoni A, Baldarelli M, et al. Is laparoscopic fiberoptic choledochoscopy for common bile duct stones a fine option or mandatory step? Surg Endosc 2010; 24: 547-53.
- Clayton ES, Connor S, Alexakis N, Leandros E. Metaanalysis of endoscopy and surgery versus surgery alone for common bile duct stones with gallblader in situ. Br J Surg 2006; 93: 1185-91.
- 9. Karaliotas C, Sgourakis G, Goumas C, et al. Laparoscopic common bile duct exploration after failed endoscopic stone extraction. Surg Endosc 2008; 22: 1826-31.
- 10. Fitzigibbons RJ, Gardner GC. Laparoscopic surgery and common bile duct. World J Surg 2001; 25: 1317-24.
- 11. Poulose BK, Speroff T, Holzman MD. Optimizing choledocholithiasis management: a cost-effectivness analysis. Arch Surg 2007; 142: 43-8.
- 12. Waage A, Stromber C, Leijonmack CE, Arvidsson D. Long-term results from laparoscopic common bile duct exploration. Surg Endosc 2003; 17: 1181-5.
- 13. Dindo D, Demartines N, Clavien PA. Classification of surgical complications. Ann Surgery 2004; 240: 205-13.
- 14. Zhang HF, Hu SY, Zhang GY, et al. Laparoscopic primary choledochorrhaphy over endonasobilary drainage tubes. Surg Endosc 2007; 21: 2115-7.
- 15. Topal B, Vromman K, Aerts R, et al. Hospital cost categories of one-stage versus two-stage management of common bile duct Stones. Surg Endosc 2010; 24: 413-6.
- 16. Gurusamy KS, Samraj K. Primary closure versus T-tube drainage after open common bile duct exploration. Cochrane Database Syst Rev 2007; 1: CD005640.
- 17. Lyass S, Phillips EH. Laparoscopic transcystic common bile duct exploration. Surg Endosc 2006; (Suppl 2): 441-5.
- 18. Decker G, Borie F, Millat B, et al. One hundred laparoscopic choledochotomies with primary closure of the common bile duct. Surg Endosc 2003; 17: 12-8.
- 19. Chander J, Vindal A, Lal P, et al. Laparoscopic management of CBD stones: an Indian experience. Surg Endosc 2011; 25: 172-81.
- 20. Noble H, Whitley E, Norton S, Thompson M. A study of preoperative factors associated with a poor outcome following laparoscopic bile duct exploration. Surg Endosc 2011; 25: 130-9.
- 21. Chiarugi M, Galatioto C, Decanini L, et al. Laparoscopic transcystic exploration for single-stage management of common duct stones and acute cholecystitis. Videosurgery Miniinv 2012; 26: 124-9.
- 22. Ido K, Isoda N, Taniguchi Y, et al. Laparoscopic transcystic cholangioscopic lithotripsy for common bile duct stones during laparoscopic cholecystectomy. Endoscopy 1996; 28: 431-5.
- 23. Kopeć B, Marciniak R. Causes and frequency of conversion during laparoscopic cholecystectomy in own material. Videosurgery Miniinv 2010; 5: 132-8.
- 24. American Society for Gastrointestinal Endoscopy. The role of endoscopy in the evaluation of suspected choledocholithiasis. Gastroint Endosc 2010; 71: 1-7.
- 25. Yang MH, Chen TH, Wang SE, et al. Biochemical predictors for absence of common bile duct stones in patients undergoing laparoscopic cholecystectomy. Surg Endosc 2008; 22: 1620-4.

- Peng WK, Sheikh Z, Paterson-Brown S, et al. Role of liver function tests in predicting common bile duct stones in patients with acute calculous cholecystitis. Br J Surg 2005; 92: 1241-7.
- 27. Barkun AN, Barkun JS, Fried GM, et al. Useful predictors of bile duct stones in patients undergoing laparoscopic cholecystectomy. Ann Surg 1994; 220: 32-9.
- 28. Onken JE, Brazer SR, Eisen GM, et al. Predicting the presence of choledocholithiasis in patients with symptomatic cholelithiasis. Am J Gastroenterol 1996; 91: 762-7.
- 29. Einstein DM, Lapin SA, Ralls PW, et al. The insensivity of sonography in the detection of choledocholithiasis. Am J Roentgenol 1984; 142: 725-8.
- 30. Cronan JJ. US diagnosis of choledocholithiaisis: a reappraisal. Radiology 1986; 161: 133-4.
- 31. Mitchell SE, Clark RA. A comparison of computer tomography and sonography in choledocholithiasis. Am J Roentgenol 1984; 142: 729-33.
- 32. Pedersen OM, Nordgard K, Kvinsland S. Value of sonography in obstructive jaudnice. Limitation of bile duct caliber as an index of obstruction. Scand J Gastroenterol 1987; 22: 975-81.
- 33. Baron RL, Stanley RJ, Lee JKT, et al. A prospective comparison of the evaluation of biliary obstruction using computer tomography and ultrasonography. Radiology 1982; 145: 91-8.
- 34. Andriulli A, Loperfido S, Napolitano G, et al. Incidence rates of post-ERCP complications: a systematic survey of prospective studies. Am J Gastroenterol 2007; 102: 1781-8.
- 35. Cotton PB, Garrow DA, Gallagher J, et al. Risk factors for complications after ERCP: a multivariate analysis of 11,497 procedures over 12 years. Gastroint Endosc 2009; 70: 80-8.
- Reinders JSK, Goud A, Timmer R, et al. Early laparoscopic cholecystectomy improves outcomes after endoscopic sphincterotomy for choledochocystolithiasis. Gastroenterology 2010; 138: 2315-20.
- Bostanci EB, Ercan M, Ozer I, et al. Timing of elective laparoscopic cholecystectomy after endoscopic retrograde cholangiopancreaticography with sphincterotomy: a prospective observational study of 308 patients. Langenbecks Arch Sur 2010; 395: 661-6.
- 38. Verbesey JE, Birkett DH. Common bile duct exploration for choledocholithiasis. Surg Clin N Am 2008; 88: 1315-28.
- 39. Gurusamy KS, Samraj K. Primary closure versus T-tube drainage after laparoscopic bile duct stone exploration. Cochrane Database Syst Rev 2007; 1. CD005641.

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