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# Laparoscopic One-Stage vs Endoscopic Plus Laparoscopic Management of Common Bile Duct Stones – A Prospective Randomized Study

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## 1. Introduction

The incidence of gallstones is rather high and is referred as approximately 13%-17% among the western population, [Bateson, 2000; Barbara et al., 1987; Everhart et al., 1999; Pixley et al., 1985]. It is well known that most of the people with gallstones are asymptomatic and often they are absolutely unaware of their presence, it is even referred that no more than 15-20% of them has the probability of suffering from a biliary colic later on [Attili et al., 1995], which, once occurred, could recur more easily causing sometime serious complications, such as pancreatitis by stone's migration and biliary obstruction, that over a 10-year period can be expected to occur in 2-3% of patients with initially silent gallbladder stones [Gracie & Ransohoff, 1982].

The incidence of common bile duct (CBD) stones has been reported as ranging between 5% to 18% of patients undergoing cholecystectomy for gallstones, and patients with symptoms suggestive of choledocholithiasis have an even higher incidence, also increasing with age [Martin et al., 2006]. Because of the continuous developing of the diagnostic and therapeutic techniques from the introduction of intra-operative cholangiography by Mirizzi in 1932, the choice of the most effective strategy in the management of the common bile duct (CBD) stones associated with gallstones is object of close discussions far from any conclusive agreement. The new diagnostic techniques as magnetic resonance cholangiography (MRC) and endoscopic ultrasound (EUS), give the opportunity to visualize the biliary tree without any invasive exploration of the ducts and share the same idea as the minimally invasive laparoscopic surgical approach. They are progressively evolving as well as the standard of care for the management of common bile duct (CBD) stones, historically performed via

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laparotomy, which over the past decade-and-a-half has changed from open cholecystectomy with common bile duct exploration through intraoperative cholangiography or choledocoscopy, to the routine availability of endoscopic retrograde cholangioscopy (ERC) with endoscopic sphincterotomy (EST) for common bile duct (CBD) stone extraction performed before or after surgery, open in the past and laparoscopic from almost fifteen years, [Clayton et al., 2006]. However, endoscopic sphincterotomy for bile duct stones complains about a disappointing 8%–10% rate of long-term biliary complications including recurrent or residual ductal stones, cholangitis, stenosis of the papilla, and biliary pancreatitis [Paganini et al., 2007]. Macadam&Goodall, [2004] referred a high 28% rate of late, rather frequent symptoms related to low-grade cholangitis following papillosphincterotomy. Consequently the potential sequence of late persistent cholangitis should be regarded as a matter of concern, particularly in fertile female patients.

More recently laparoscopic exploration of the common bile duct (LCBDE) has been introduced for managing patients with suspected CBD stones, which allows the intraoperative definite diagnosis and the treatment at the same time, if necessary. As referred in the New Guidelines Address Management of Common Bile Duct Stones [Williams et al., 2008] the consequences are that “clinicians are now faced with a number of potentially valid options for managing patients with suspected CBDs”.

Consequently the primary challenge in the management of common bile duct stones in association with gallstones nowadays is to select the best strategy with regard to success, morbidity and cost-effectiveness, [Clayton et al., 2006].

Endoscopy for common bile duct stones and surgery, mainly laparoscopic, for gallstones have been widely adopted as the preferred approach, because the results in terms of success rate, morbidity and mortality tend to overlap those of the whole surgical open approach for gallstones and common bile duct stones offering the undeniable advantages of being less invasive. The ultimate evolution of the association of laparoscopic cholecystectomy with endoscopic retrograde cholangioscopy (ERC) + endoscopic sphincterotomy (EST) was the rendez vous approach performed in a single stage operative procedure together by the surgical and the endoscopic teams, which has shown an overlapping outcome compared to other kinds of association between surgical and endoscopic procedures. Since it is commonly accepted that only a low rate of patients suffering from gallstones and undergoing laparoscopic cholecystectomy are likely to have bile duct stones identified, this procedure to be cost effective needs a definite preoperative diagnosis of common bile duct stones using the modern techniques of imaging such as MR and EUS, which can improve the likelihood of stones being found to over 90%, [Liu et al., 2001; Williams et al., 2008].

Nevertheless in the literature some limits concerning the use of endoscopy are referred like the number and the size of stones, the incidence of complications of ERC + EST occurring in 5%- 8% of cases, with mortality rates of 0.2% to 0.5% from more difficult procedures or the necessity of multiple sessions to clear completely the common bile duct requiring the use of expensive equipment and accessories. This strategy statistically increased the likelihood of complications as two or more procedures sometime should be performed in a patient to clear up successfully the duct, [Byrne et al., 2009]. As recently referred by Sjer et al. [2010], the ideal technique of common bile duct stones clearing should be minimally invasive, easy to perform, reliably clear all stones from the CBD, obtaining as well the earliest possible discharge from the hospital and leaving the patient with an undisturbed function of the

papilla Vateri. The routine adoption of laparoscopic common bile duct exploration (LCBDE) associated with cholecystectomy has been promoted by the constant improvement in techniques and expertise of surgeons who are increasingly confident with laparoscopic hepato-biliary surgery and are deeply interested to bring back the whole procedure within the surgical approach. This approach seems to fulfill almost all the previous issues, nevertheless some negative aspects should be considered as the evidence that laparoscopic common bile duct surgery is time consuming and requires a rather long lasting learning curve of the whole staff of an advanced laparoscopic procedure, as well as fluoroscopic equipment and expensive accessories for the procedure that moreover may not be feasible in cases where the CBD diameter is  $<6$  mm., [Fitzgibbons & Gardner, 2001]. Our group, as other centers, adopted the procedure of single-stage laparoscopic cholecystectomy (LC) plus common bile duct exploration, with stone extraction performed by different techniques, and a randomized prospective study has been designed to compare it with the standard double-stage procedure based on preoperative endoscopic clearance followed by a laparoscopic cholecystectomy, with the aim of assessing the more safe and successful therapy for the patient.

## 2. Materials and methods

In our unit from January 1996 until June 2010, 918 consecutive patients underwent elective or acute laparoscopic cholecystectomy, and ductal biliary stones were detected in 121 patients (13.1%). These patients were treated with the two-stage procedure until 2002, at that time laparoscopic common bile duct exploration and treatment, if necessary, was introduced following a decision analysis performed with the aim of evaluating cost/benefits, efficacy, recurrence, compliance of the patients as referred in the literature, [Urbach et al., 2001].

Consequently 124 out of 534 consecutive patients with evidence (36 patients) or suspicion (88 patients) of duct stones as result of a diagnostic program including US scanning, MR cholangiography and biochemical investigations, were randomly assigned to one of the two selected procedures: one-stage surgical procedure (group 1) and two-stages endoscopic + surgical procedure (group 2). All patients were informed about each procedure and involved technology and they were also asked for their consent to be randomized in the group 1 or in the group 2 and signed the consent forms. Exclusion criteria against laparoscopic common bile duct exploration were suspicion of malignancy, stone impaction, evidence of severe pancreatitis and/or cholangitis or unfitness for general anesthesia, consequently from this series were excluded three patients.

The two groups had comparable demographic and clinical profiles, (tab. 1). The presence of stones was confirmed in 39 out of 62 pts. of the two-stage group who underwent preoperative ERCP and sphincterotomy for clearing the CBD and after 2-5 days underwent a successful laparoscopic cholecystectomy. In the one-stage group stones were found in 45/62 pts. in whom an intraoperative ductal exploration was attempted via the cystic duct that was successful in 55 patients, (88.7%) and required a choledochotomy in 7 patients (11.3%), because of the size of the stones or unexpected intraoperative difficulties.

Stones were completely removed through the cystic duct in 29 patients while in 16 patients through the previous or a newly performed choledochotomy, using Dormia and/or Fogarty catheters. The transcystic approach failed because of the following reasons: the cystic duct was too small or fraile, the stones were larger than 1 cm or in a number greater than five or proximal to the confluence into the hepatic duct. The techniques of transcystic catheter

insertion to extract the stones include cystic duct dilation, washing, exploration with biliary balloon catheters or wire baskets, final check with a cholangiography at the end of the procedure. In case of choledocotomy a biliary endoscopy was also performed in 9/16 patients, with an Olympus flexible choledoscope CHF-CB 30S, in order to remove stones with a catheters under direct vision or to check the duct after the removal of the stones. All patients underwent a control cholangiogram to ensure that duct's clearance was successfully done and that the papilla was patent to contrast dye passage into the duodenum. External biliary drainage with T tube and postoperative cholangiography was performed in 9 patients. All patient had an external transparietal subhepatic drainage at least for 24 hours, at most for four-five days in those patients in which T-tube drainage was inserted, to control potential early or late persistent biliary leak. T tube was removed after a negative control with a transKehr cholangiography performed within 3-4 weeks from the previous surgery. The laparoscopic procedure was completed in 121 patients (97.6%). Patients were followed up for 1-9 years (mean 4.5 yrs.), visiting them in the outpatient clinic or interviewing by telephone calls after the first year.

2.1 Operative procedure

The laparoscopic cholecystectomy was performed with a standard four-trocar technique using the transumbilical open approach according to the Hasson technique. In case of preoperative evidence or suspicion of CBD stones, a small quantity of diluted contrast solution was injected, (Ultravist-300, Schering A.G., Berlin, Germany, 50% diluted with a 0.9% saline solution), performing the first cholangiography through the incision of the cystic duct made close to the confluence into the common duct to facilitate the passage of the operative cholangiogram catheter 4.5 Fr x 45.7cm (TAUT inc. Geneva, Il 60134 USA).

Preoperative clinical variables	LCBDE (n = 62)	ERCP +LC (n = 62)	p Value
Age (years)	53 ± 13	55 ± 15	NS
Gender (females, %)	76	79	NS
ASA	2 ± 1	2 ± 1	NS
Biliary symptoms (%)	75	70	0.01
Cholecystitis (%)	14.8	18.1	0.05
Jaundice (%)	6	20	0.01
Pancreatitis (%)	6.4	4.8	NS
Cholangitis (%)	0	1.6	0.05
Previous abdominal surgery (%)	29	32	NS

Table 1. Comparison of clinical demographics of patients in LCBD exploration and treatment group and in ERCP and LC group.

When CBD stones were detected a non-Radiopaque Karlan Balloon Catheter: 4 Fr. 2-Lumen, 60 cm, (Arrow percutaneous laparoscopic cholangiography set CS-01701; Arrow International Europe) was introduced on the anterior axillary line under the right costal margin to allow an appropriate access to the cystic duct, to remove the stones, using a flexible wire guide, if necessary, through the curved guide catheter. The choledochotomy was done after a good exposure of the liver hilus pulling up and to the right the gallbladder and lifting up the round ligament, exposing the anterior wall of the duct making a longitudinal incision sometime helped by two 4/0 prolene stitches lifting up the



supraduodenal choledocus. The primary closure of the incision was done mainly with a running 4/0 prolene suture. Details of the surgical procedure (exploration, stones extraction, radiological and endoscopic control etc.), timing of the two-stage procedure, results and complications of surgical and endoscopic treatment were recorded.

## 2.2 Statistical analyses

The procedures performed in the two groups were recorded as success or failure according to the complete clearance of the CBD as showed by the final intraoperative cholangiography. The outcome of the procedures was evaluated as well, looking at different parameters: common bile duct diameter, number of stones, stone size, presence of intrahepatic stones, mean operating time, length of hospital stay. Some of these were splitted in two categories: the limit of 6 mm. was identified for the bile duct diameter, the size of 5 mm. for the stones, and the number of three for the stones. In significance testing Fischer's exact test was used for dichotomized discrete variables and the nonparametric Wilcoxon method for comparisons between means, [Stromberg et al., 2008].

## 2.3 Definition of success

It has been defined as primary outcome measure the successful removal of gallbladder and common bile duct clearance performing the procedures of treatment, and as secondary outcome the results in terms of specific and generic complications such as bleeding, cholangitis, bile leak or fistula, surgical-site infection, late recurrency and other medical complications.

## 3. Results

Removal of the stones in the two groups was successfully done in 79 patients (94%), mortality directly related to the procedures was nil (1 cardiac failure at 6 months) nor occurred major intra-operative complications in either group. In two patients, a conversion into laparotomy was necessary for intraoperative haemorrhage caused in the first by an accessory cystic artery and by a severe haemobilia in the second one. The average diameter of the common bile duct was 10.7 mm (range 6-22 mm). The mean number of stones was 3.4 (1-10). The mean operating time in the group 1 was 160 m' (range 100-280 m'), the operation lasted significantly more time in the unsuccessful procedures and in patients undergone choledocal exploration, either as first choice or in case of failure of the transcystic approach.

Obviously patients who underwent laparoscopic common bile duct exploration had a longer operating time compared with the group undergone laparoscopic cholecystectomy alone (mean time 70 m'). T tubes were applied to patients with multiple stones (>5) and CBD diameter greater than 6 mm., at risk for retained sludge, previous attacks of cholangitis or pancreatitis, poor tissue quality secondary to duct's infection. It was removed within 3-4 weeks after a trans-Kehr cholangiography without complications neither difference in comparison with primary suture of the choledocal incision, (tab. 2).

Residual CBD stones were detected in the two groups at different intervals of time, following a routine control by an abdominal ultrasonography or magnetic resonance cholangiography. In two patients of the group 1 the stones were removed successfully by

ERC and endoscopic sphincterotomy after 6 and 8 months from previous surgery, in one patient a new laparoscopic approach (LCBDE) was performed after 30 months because suffering from symptoms referred to recurrent stones. The residual stones in the two patients of the group 2 were successfully removed by a new endoscopic approach and sphincterotomy (EST), without any local and systemic complication.

	N°	Successful (%)	Failure (%)	P value
Total number of patients	84	79 (94)	5 (6)	
CBD diameter				n.s.
≤ 6mm	31	29 (93.5)	2 (6.5)	
> 6mm	53	50 (94)	3 (6)	
Mean number of stones	3.4	2.9	5.2	0.0053*
Number of stones				<0.001^
≤3	58	57 (98)	1 (2)	
>3	26	22 (85)	4 (15)	
Mean stone size (mm)	5.4	5.1	8.3	0.0045*
Stone size				<0.001^
≤5mm	61	60 (98)	1 (2)	
>5 mm	23	19 (83)	4 (17)	
Intrahepatic stones				n.s.
Yes	3	3 (100)	0	
No	81	76 (94)	5 (6)	
Mean operating time (minutes)	170m'	150m'	230m'	<0.001^
Mean length of hospital stay (2-16days)	7.1	4.5	9.0	<0.001^

\* Fischer’s exact test  
^Wilcoxon nonparametric method

Table 2. Overall results of the procedures of CBD stones removal

There was a significant increasing risk among patients with stones of diameter greater than 5 mm. compared to patients with stones of 5 mm. or less. One-stage management of duct stones was associated with a significant less morbidity than two-stage approach (8.1% vs. 14.2%), which is increasingly significant for multiple stones or stones > 5mm. Haemorrhage occurred in 4.8% (2.2% vs. 7.7%), pancreatitis in 2.4% (2.2% vs. 2.6), port site infection and cholangitis in 1.1% (in the group 2). The mean postoperative hospital stay was 7.1 days (range 2-16), and depended mainly on the surgical outcome in terms of clearing of the common bile duct i.e. success or failure of the procedure.

In the group 1, one patient, who underwent a transcystic stone extraction had a biliary leak not requiring reoperation. After 13 months one patient of the group 2 underwent a new endoscopic treatment, as she was referred to our Day Surgery Unit for a symptomatic cholangitis with evidence of biliary sludge by ultrasonographic examination at the casualty department, caused by a stenosis of the papilla Vateri as showed by a following magnetic resonance, (tab. 3).

	LCBDE (n=45)	ERCP +LC (n=39)	p Value
	N° (%)	N° (%)	
Successful	42 (93)	37 (95)	n.s.
Failure	3 (7)	2 (5)	
CBD diameter			n.s.
≤6mm	15 (33)	16 (41)	
>6mm	30 (67)	23 (59)	
Mean number of stones	3.5	3.2	n.s
≤3	32 (71)	26 (67)	
>3	13 (29)	13 (33)	
Mean stone size (mm)	5.2	5.7	n.s.
Stone size			
≤5mm	32 (71)	29 (74)	
>5mm	13 (29)	10 (26)	
Intrahepatic stones			
Yes	2	1	n.s.
No	43	38	
Postoperative complications	4 (8.8)	6 (15.3)	0.0045*
stone size    ≤5mm	1 (2.2)	2 (5.1)	<0.005^
>5 mm	3 (6.6)	4 (10.2)	
Number    ≤3	0	1	
>3	4	5	
Mean length of hospital stay (2-16days)	7.1	3.5	<0.001^

\* Fischer’s exact test  
^Wilcoxon nonparametric method.

Table 3. Comparison of the results of stones removal between the two groups

4. Discussion

The aim of this study was to evaluate the results of the treatment of common bile duct stones in patients undergoing single-stage laparoscopic management of gallstones and CBD stones performing either transcystic common bile duct exploration (TC-CBDE) or laparoscopic choledochotomy, compared to the two-stage well established and more widely used endoscopic retrograde cholangioscopy + endoscopic sphincterotomy followed by laparoscopic cholecystectomy. The analysis of the results of this prospective study, based on a randomized distribution of 124 consecutive patients in which suspicion or evidence of CBD stones was reported, emphasizes the role of mininvasive treatment of gallbladder and CBD stones, that has become the main focus of biliary surgery. Though a single center study, a comparison has been done between two procedures, with the removal of stones from CBD as primary end-point, recruiting consecutive patients affected by common bile duct stones or highly suspected of stones presence, without any selection criteria, except the exclusion caused by malignant lesions, high surgical risks or patient’s refusal to undergo surgery. They were randomly assigned either to a totally laparoscopic approach including cholecystectomy and duct exploration and treatment, if necessary, or to a double procedure: endoscopic (ERC ± EST) as first step, followed by laparoscopic cholecystectomy at different interval of time depending mainly on the outcome of the endoscopic treatment.



These are scheduled among the accepted procedures for an elective treatment, since the conservative or wait and see strategy have been ruled out. Other procedures as the association of the laparoscopic cholecystectomy with ERC + endoscopic sphincterotomy known as the rendezvous approach [Morino et al., 2006; Tricarico et al., 2002;], or the endoscopic treatment after a positive intra-operative cholangiography need more experience and good cooperation between different teams, particularly in the second issue [Hong et al., 2006], and could increase the risk of postoperative complications in both cases, included the need of a second operation if the endoscopic sphincterotomy (EST) fails, [Patel et al., 2003]. Laparoscopic common bile duct exploration as single approach, requires a longer learning curve mainly because of the possibility that the procedure could become more demanding if a laparoscopic suture should be performed when the removal of stones is done via a choledocal incision, with or without T-tube placement. The other single stage procedure is the laparoendoscopic rendezvous associating laparoscopic cholecystectomy with intraoperative endoscopic retrograde cholangiography with stone extraction as a one-time therapy for gallstones and CBD stones, that according to Morino et al., (2006) had a higher success rate (95.6% v. 80%), shorter hospital stay (4.3 days v. 8 days) and lesser cost (€ 2829 v. € 3834), compared with the two stage procedure. It was recently referred that the rendezvous technique can warrant a successful treatment even in cases complicated by cholangitis or pancreatitis, with the help of a guidewire introduced through the cystic duct into the papilla that may reduce the complications secondary to the endoscopic cannulation. With this device is possible to reduce the failure rate of the retrograde cholangiography as well as the incidence of the major complication, i.e. acute pancreatitis, of the laparoendoscopic rendezvous technique compared with the sequential ERCP and LC (5% vs. 20%), as referred by El Geidie et al., (2011) who had worse results (no significant difference in failure rate) probably due the non use of the guidewire. Nevertheless with this approach it is impossible to avoid the potential complications linked to the endoscopic sphincterotomy, [Borzellino et al., 2010]. As reported before the major limits lie on the management of endoscopy together with surgery in the operating theatre, and these problems have discouraged the diffusion of this combined approach throughout surgeons interested to this disease, [Meyer et al., 1999]. It should be outlined that the rendezvous procedure should be adopted only in patients with a positive evidence of common bile duct stones, and the ideal would be to predict CBD stones without invasive tests in order to avoid unnecessary and sometime risky procedures, as today magnetic resonance cholangiography actually can obtain. It is likewise necessary to refer that skilled surgeons are able to achieve an overall satisfying outcome, performing the rendez vous procedure, which is quite overlapping with those of the one stage total laparoscopic approach, also from the point of view of the residual stones' rate, [Tranter & Thompson, 2002].

On the other hand in the literature the A.A. generally agree that the first endoscopic step of the two stage procedure is associated with a high complication rate of about 10%, mainly acute pancreatitis (3%) and a mortality rate of 4%, which could increase respectively to a maximum of 16% and 6%, by the addition of the potential complications following the surgical step, [Hong et al., 2006]. This difference could be partially explained by the length of the interval between the two procedures, which is not well defined, as even in the multicenter trial by the European Association for Endoscopic Surgery (EAES) the interval between endoscopic papillosphincterotomy and laparoscopic cholecystectomy was not specified, [Cuschieri et al., 1999]. It is referred that patients awaiting for laparoscopic cholecystectomy risk a high rate of readmissions and complications due to acute cholecystitis, pancreatitis, empyema and cholangitis; de Vries et al., [2005 ], showed that in

case of delayed cholecystectomy, done more than two weeks after endoscopic sphincterotomy, there is a higher conversion rate, increasing from 4% when LC was done within 2 weeks, to 31% between 2 and 6 weeks, and 16% after 6 weeks. A consequence of these considerations was the policy of leaving in situ the gallstones, avoiding the second laparoscopic approach, a sort of wait and see strategy based on the results of retrospective studies which described a relatively low incidence (5–12%) of biliary complications or recurrent symptoms in patients not undergone routine cholecystectomy following the endoscopic removal of common bile duct stones, [Byrne et al., 2009]. Nevertheless there is a positive consensus on the indication to primary endoscopic sphincterotomy in case of suppurative cholangitis, severe pancreatitis, high-risk patients, and patients who had previous cholecystectomy, [NIH Consensus Statements, 2002]. In our study patients with gallstones did not undergo any invasive diagnostic exploration if not in case of history of jaundice, gallstone pancreatitis with elevated amylase or lipase, elevated bilirubin level, abnormal liver function test results, dilated CBD on preoperative ultrasonography. Magnetic resonance cholangiography was performed when were present one or more criteria above referred, which as well indicated the necessity to perform an intraoperative cholangiography (IOC). The presence of stones was confirmed in 84 out of 124 patients (68%) who entered in the prospective trial and subsequently were explored by IOC or ERCP, the rate of stones was similar in the two groups without significant difference between groups, (72% vs. 60%;  $p < 0.05$ ), confirming that they were substantially homogeneous. The overall evaluation of the outcome of the two procedures shows that two factors mainly influence the results of the treatment: the number and the size of stones, neither CBD diameter neither intrahepatic stones influenced the outcome of the procedures. Strömberg et al., [2008] confirmed previous results of Petelin, [2003], who referred that patients with stones larger than 5 mm had a significant threefold increased risk of failure in stone clearance compared to patients with stones  $\leq 5$  mm., and suggested a causal relation between large stone size and an increased risk of failure in stone clearance during LTCE. As consequence of the difficulties come across the procedures, postoperative complications were significantly higher in patients unsuccessfully treated. Nevertheless in the overall series postoperative morbidity was reasonably low and there was no postoperative mortality among the patients enrolled in this study. All these data agree with most of the past and recent reports in the literature [Campbell et al., 2004; Kharbutli & Velanovich, 2008], confirming the indications of the European Association for Endoscopic Surgery for TC-CBDE that are limited to stones that are smaller than the size of the cystic duct [Paganini et al., 2007]. However in our experience the dilation of the cystic duct with a balloon catheter, as usually done to easy the passage into the choledochus, allows to carry out successfully the transcystic procedure for extracting stones even larger than cystic duct, moreover because of their friability. Nevertheless the choledocotomy, performed by elective choice or compelled by intraoperative complication or difficult removal, did not imply an increase of risks and the rate of successful extraction of stones in the two groups is quite similar, without any difference statistically significant (93% vs. 95%). The learning curve of laparoscopic duct exploration (LCBDE) through choledocotomy is not negligible, but once achieved a sufficient expertise it can be safely performed during the one-stage procedure without any evidence for longer hospitalization caused directly by the surgical maneuvers on common duct. No biliary peritonitis or postoperative cholangitis were observed in the one stage group and some minor complications (hyperamylasemia, port site infection, biliary leak etc.) were treated by a conservative therapy and did not require surgical

measures, as well as they did not lengthen significantly the mean hospital stay, as also showed by the results of different authors, who did not report significant increase of common duct lesions by surgical and/or instrumental maneuvers [Decker et al., 2003; Lezoche & Paganini, 1995; Paganini et al., 2007]. However the transcystic cannulation of the common bile duct must be regarded as the primary approach to explore CBD, and it can be done as showed by our experience in agreement with several authors, because it is less invasive than laparoscopic choledochotomy.

Nevertheless when stones are larger than 6 mm. or located above the cystic duct choledochotomy could be indicated or sometime compelled by the failure of the transcystic exploration and/or stones removal. The extraction of the stones can be very difficult when they are impacted but in most cases gentle maneuvers with atraumatic Croce forceps through the choledochotomy or irrigation with saline solutions can achieve, after some efforts, a successful duct clearing. However in case of failure biliary Fogarthy catheters or Dormia basket could be used blindly or under vision introducing a choledoscope, through the cystic duct or more easily through the choledochotomy, depending, of course from the diameter of the endoscope available. It was referred that the mean rate of failure because of residual stones after laparoscopic exploration and treatment of duct stones is about 5%-7%, that is quite similar to the rate referred by Moreaux, [1995], following open biliary surgery. The use of choledochoscopy can reduce to 2.8% the rate of residual stones according to the experience of Berthou et al., [2007], which is remarkably lower than the incidence ranging from 17% to 35% of residual stones following endoscopic treatment [Lenriot et al., 1993; Tranter & Thompson, 2002]. Recently it has been confirmed that employing the Dormia laparoscopic basket under control of a choledoscope the CBD removal is safer and more effective as far as postoperative complication and residual stones are concerned, particularly in comparison with endoscopic procedure burdened by a 10% rate of residual stones, which is significantly higher and advised to perform non surgical treatment only in case of high risk patients, [Campagnacci et al., 2010]. There is no doubt that the direct approach to CBD can eliminate any problem caused by high number or large diameter of the stones, or their intrahepatic placement. In our experience about 35% of stones extraction was accomplished performing a choledochotomy, sutured at the end of the procedure mainly with a primary running suture. A closure over a T tube with an external biliary drainage and postoperative cholangiography was done in 9 patients, without differences in postoperative complication rate, except the necessity of a cholangiographic control following surgery, to check the duct's patency with normal flow of the contrast into the duodenum, and even the potential presence of residual stones, sludge or fragments of stones, which were flushed down through the papilla with saline injection, provided that there was no leak around the catheter. The procedure was repeated before the removal of the T tube, which did not cause any major problem, such as peritonitis or biliary fistula, nor minor local or general complication.

In our experience the use of endobiliary T tube did not affect the outcome in terms of complications, even if we realize that the number of our patients is relatively poor and does not allow any definite conclusion. However in the literature it is referred that the most frequent early complications after LCBDE derive from biliary leaks or infections and are caused mainly by the presence of biliary drainage, that could also cause late biliary stricture, [Decker et al., 2003; Thompson & Tranter, 2002; Alhamdani et al., 2008]. Thompson and Tranter [2002] reported a complication rate of 16% following the use of the T tube vs. 5% for primary closure. However our results support those of Paganini and Lezoche, [1998] and

Berthou et al., [2007], who found a similar incidence of biliary complications following both the procedures. It is generally accepted that a closure over a T tube is to prefer when the CBD is inflamed because of recurrent cholangitis, [Karaliotas et al., 2008], or dilated and consequently at risk of postoperative atonia and leakage, it could likewise allow for postoperative radiographic control and in case even for extraction of missed or retained stones. There are also some studies comparing primary closure versus T tube drainage which refer similar rates of complications, but definitely it was showed a shorter operating times and a consistent trend toward shorter hospital stays in favour of the primary closure, [Kanamaru et al., 2007; Jameel et al., 2008].

The incidence of residual or recurrent biliary stones, which has been referred as failure of the procedures in table 1, is quite similar in the two groups (7% vs. 5%), with a rate of residual stones sensibly lower in the LCBDE group (4.1%). These data are slightly higher than those referred by Chander et al., with a rate of 2.7%, [2011], and by Berthou et al., [2007], of 2.8%, Paganini et al., [2007], of 3.1%, Hong et al., [2006], of 3.5%, but are lower than the rate of 6.3% of Schreurs et al., [36], and all the same are significantly lower than the data referred in the literature of the CBD stones recurrent rate of 9%-12% found at IOC after previous ERCP+EST and LC, [Pierce et al., 2008; Campagnacci et al., 2010].

Nowadays the patients suffering from gallstones with CBD stones scheduled to undergo laparoscopic cholecystectomy may be treated by peri-operative ERCP or managed by LCBDE associated with cholecystectomy in a single surgical step. The "Guidelines on the management of common bile duct stones (CBDS)" [Williams et al., 2008], asserted that "There is no evidence of a difference in efficacy, morbidity or mortality when these approaches are compared, though LCBDE is associated with a shorter hospital stay. It is recommended that the two approaches are considered equally valid treatment options, and that training of surgeons in LCBDE is to be encouraged. (Evidence grade I b. Recommendation grade A.)". It seems that it is widely accepted the evidence from randomised control trials that the outcomes of the one- and two-stage procedures are comparable, some arguments in favour of laparoscopic exploration of the biliary duct could be the evidence of a shorter hospital stay and a better cost-effectiveness as showed by Urbach et al., [2001]. However data from the Cochrane Hepato-Biliary Group, [Martin et al., 2006], don't support any definite evidence of superiority in terms of efficacy, morbidity and mortality of one procedure over another, while the metanalysis of the literature had showed clearly that open biliary surgery was significantly superior to ERC+Endoscopic sphincterotomy in achieving CBD stone clearance.

Recently the Practice/Clinical Guidelines published on 01/2010 by the Society of American Gastrointestinal and Endoscopic Surgeons: "SAGES guidelines for the clinical application of laparoscopic biliary tract surgery" in the chapter dedicated to the management of choledocholithiasis stated that:

- There are several approaches and current data does not suggest clear superiority of any one approach. (Level I, Grade A).
- Laparoscopic transcystic common bile duct exploration is frequently successful, but may be hampered by anomalous anatomy, proximal stones, strictures and large or numerous stones. (Level II, Grade B).
- Laparoscopic choledochotomy requires advanced laparoscopic skills, but has good clearance rates; the incision may be closed over a T tube, an exteriorized transcystic drain, or primary closure with or without endoluminal drainage. (Level II, Grade B).



- ERCP with stone extraction may be performed selectively before, during or after cholecystectomy with little discernable difference in morbidity and mortality and similar clearance rates when compared to laparoscopic common bile duct exploration, though routinely performed preoperative ERCP will likely result in unnecessary procedures with higher than acceptable mortality and morbidity rates. (Level I, Grade A).

On the basis of this evidence based medicine, our experience from the results of this trial suggests that biliary stones should be treated again by surgeons in first approach, as the endoscopic procedures do not automatically guarantee the complete cleansing of choledocus from stones or the absence of endoscopically related complications. Consequently a surgeon used to perform laparoscopic advanced procedures and dedicated to the management of hepato-biliary diseases, should improve his skill in the intraoperative management of the common bile duct, because the treatment of the individual patient needs an available and expert surgical team to assure good results in terms of success, costs, and length of hospital stay.

The experience resulting from this prospective study supports the aim of demonstrating that laparoscopic surgery of cholecystocholedocal stones is as safe as the procedure associating LC with endoscopic removal of ductstones, but in the great majority of cases it avoids an unnecessary double admission to the hospital services, lowers the risks connected with a double procedure, and as far as the outcome of the follow-up, though not too extended, it involves a low recurrence rate, as already showed in a study with a long-term follow-up (118 mo.) by Paganini et al., [2007]. Looking at the clinical effectiveness, and at the cost/benefits ratio, these two procedures should be considered therefore between the most useful treatment of biliary stones disease, but the single surgical approach has the advantage of taking care of the papilla Vateri avoiding unnecessary and sometimes dangerous sphincterotomy, [Sugiyama & Atomi, 2002].

Differently from the observation referred by Hong et al., [2006], about the use of the cholangioscope to remove the stones, because it could cause a waste of time, we would stress the opinion that all the techniques and devices used in the open approach to common bile duct, which are currently available in the up-to-date models, should be as well at disposal of the laparoscopic exploration of the bile duct, and used by the surgeon depending on the needs more than on predisposed patterns. The ability of managing even difficult situations consists in choosing the better way to explore the duct and to remove the stones if identified, without rejecting any helpful option. Actually most of the authors agree on the necessity of an adequate training of the surgeon facing with laparoscopic exploration of common duct in order to allow that this procedure could become the first choice approach to biliary stones disease, preventing the occurrence of early and late complications. Our study reaches a collateral not prevented aim, demonstrating that it is possible to obtain a successful surgical treatment adopting the transcystic exploration as first-line approach, that was successful in managing common bile duct stones in almost 70% of cases and that opening the common duct in case of difficulties or failure actually increases the overall success rate of the surgical approach. This confirms the conclusion of the study of Hanif et al., [2010], who encouraged surgeons to learn and apply both the procedures when they perform the one stage laparoscopic common bile duct exploration.

## 5. Conclusions

The significant and progressive improvements during the last decade of the diagnostic equipments associated with a definite trend to limit, as far as possible, any invasive



instrumental exploration in favour of the digital work out of the images registered by ultrasonography and magnetic resonance, has shown that it is possible to achieve excellent diagnostic results which allow a correct therapeutic approach. In a similar way the applications of new technologic devices, mainly dedicated to laparoscopic surgery, in association with the increasing diffusion of intraoperative surgical maneuvers borrowed from open surgery such as cholangiography, X-guided explorations, US scanning and others, allow the surgeons to increase their confidence with advanced laparoscopic surgery, while keeping the concepts related to a miniinvasive attitude. This study demonstrates that it is possible to deal with gallstones and CBD stones at the same time, treating them with only one surgical procedure, avoiding unnecessary damage to the papilla Vateri as well as the risk of increasing complications caused by the potential addition of the complications of the endoscopic sphincterotomy to the laparoscopic cholecystectomy, (sphincterotomy, incidentally, was a matter of violent discussions between surgeons in the past decades), and achieving a complete clearing of the common bile ducts with a low rate of residual or recurrent stones. In our study CBD clearing was done in some cases with the help of the choledoscope, which is a safe but not crucial procedure, provided that several tricks can be used to achieve the same results, from gentle papillary pneumatic dilatation, to flush saline irrigations in association with intraductal lidocaine or intravenous glucagon administration. The peculiar friability of bile stones in the majority of cases helps the happy outcome of the whole procedure, which can be done for the most part by the transcystic route, as clearly showed by our results. Particularly the comparison between the totally surgical and the mixed endoscopic plus surgical treatment in this study did not showed a definite statistical advantage of one over the other, but it demonstrates that the one stage laparoscopic approach is able to solve the problem without mortality, with a low rate of morbidity and long distance sequences, residual stones included and finally with an earlier recovery and return to the normal activity of the patient. It is useful to outline that the one stage surgery does not complain of any of the peculiar biliary complication as cholangitis, papillary stenosis or recurrent pancreatitis referred to the endoscopic sphincterotomy, as the results our follow-up show. However we agree with the opinion that the two procedures are not in conflict each other, because it is possible to distinguish different indications, namely the general conditions of the patients, which could contraindicate a longer surgical approach, such as the laparoscopic exploration and cleaning of the common bile duct, particularly in case of previously recognized necessity of performing a choledocotomy because of size, number, position of the stones, or the local acute complications like cholangitis or stone impaction, with whom endoscopic treatment with sphincterotomy and or naso-biliary drainage more easily can deal successfully. In conclusion nowadays LCBDE is a safe and effective procedure that can be regarded as the first option approach to the treatment of patients affected by gallstones in association with CBD stones, in the hands of well experienced miniinvasive surgeons.

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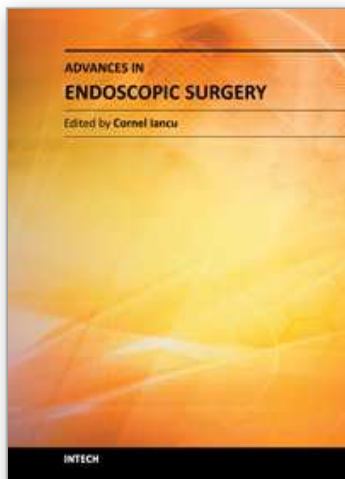
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Surgeons from various domains have become fascinated by endoscopy with its very low complications rates, high diagnostic yields and the possibility to perform a large variety of therapeutic procedures. Therefore during the last 30 years, the number and diversity of surgical endoscopic procedures has advanced with many new methods for both diagnoses and treatment, and these achievements are presented in this book. Contributing to the development of endoscopic surgery from all over the world, this is a modern, educational, and engrossing publication precisely presenting the most recent development in the field. New technologies are described in detail and all aspects of both standard and advanced endoscopic maneuvers applied in gastroenterology, urogynecology, otorhinolaryngology, pediatrics and neurology are presented. The intended audience for this book includes surgeons from various specialities, radiologists, internists, and subspecialists.

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