

Common bile duct lithiasis: therapeutic approach



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INTRODUCTION: *Treatment of cholecysto-choledocholithiasis has been revisited from the standpoint of either endoscopic or laparoscopic mini invasive approach. A standard diagnostic-therapeutic procedure has not been unanimously defined.*

PATIENTS AND METHODS: *Since 1997 to 2011 we have treated 924 patients: 555 gallbladder lithiasis, 276 acute biliary pancreatitis and 93 choledocholithiasis (without pancreatitis). We have compared, by the review of the literature, our results of two stage endoscopic stones removal followed by laparoscopic cholecystectomy versus one stage laparo-endoscopic rendez vous technique/VLC and laparoscopic approach alone.*

RESULTS: *In our experience endoscopic removal of stones have been performed in 82 patients (88.17%); 11 patients (11.82%),not eligible for endoscopic approach, have been submitted to laparotomic therapy. In sum preoperative ERCP/ES with CBD cleaning followed by VLC, not with standing the valid results of laparoscopic approach alone remains the strategy more frequently applied in clinical practice, because the good results.*

CONCLUSIONS: *The results of the treatment of CBD lithiasis of sequential laparo-endoscopic approach (two or one stage) and of laparoscopic approach alone are roughly overlappable. Therefore the first has remained the treatment of reference and comparison in all the clinical evaluation of different procedure.*

KEY WORDS: Bile duct lithiasis, Common bile duct.

Introduction

Treatment of cholecystocholedocholithiasis has been revisited from the standpoint of either endoscopic or laparoscopic mini-invasive approach. A standard diagnostic-therapeutic procedure has not been unanimously defined. In particular it is discussed when the diagnosis of choledocholithiasis must be necessarily defined: before

surgery or during the surgery phase of cholecystectomy. Also the way of preferential access for the removal of stones is not unanimously established: endoscopic transpapillary or laparoscopic choledochotomy. The aim of this study is to evaluate the results of our two stage laparoscopic-endoscopic sequential approach and to compare them with the data of one stage laparoscopic-endoscopic management and also of laparoscopic approach alone (intraoperative cholangiography (IOC), choledochotomy, etc.)

Patients and Methods

In the period September 1997- December 2011 we have treated 924 patients with biliary lithiasis: 555 lithiasis of gallbladder, 276 acute biliary pancreatitis and 93 choledocholithiasis without pancreatic involvement. In patients with choledocholithiasis without pancreatitis, the diag-

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nosis was definite in 75% of the cases; in the remaining 25% a diagnosis of suspicion was formulated. However, we would like to point out that in the first period (1997-2002) instrumental diagnosis was based on ultrasound/computed tomography (US/CT) while in the following period (2003-2011) magnetic resonance cholangiopancreatography (MRCP) has been employed. The diagnosis of certainty was formulated in the presence of evident lithiasis to the US/CT/MRCP and/or cholestatic icterus for more than 72 hours. The suspicion of choledocholithiasis instead was based on previous biliary colics with icterus, altered indexes of cholestasis, common bile duct (CBD) dilatation at US greater than 8 mm. We have verified, with statistical method, the validity of clinico-instrumental data as predictive factors of lithiasic involvement of CBD. The anamnestic data (biliary colics, jaundice, fever, etc) even if correctly estimated, have not been included in the statistical analysis because relating to transitory clinical pictures not present at the moment of our appraisal; moreover, these data badly lend themselves to an objective appraisal. Therefore, we have estimated, in 35 of the 93 patients with certain or suspect diagnosis of choledocholithiasis, the results of laboratory and instrumental examinations relating to cholestasis: alkaline phosphatase, gamma-GT, direct bilirubin, dilatation of the CBD. Moreover the results of serum lipase, amylase and transaminases (AST, ALT) have been added. We have submitted these data to univariate and multivariate analysis using exact Fisher test (95% CI). The objective of this evaluation has been to characterize the tests with predictive function of choledocholithiasis. Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) and stones/sludge removal has been the therapy of choice for choledocholithiasis. All the 93 patients have been submitted to ERCP/ES to confirm the diagnosis and for endoscopic removal of stones. Afterward, during the same hospitalization, 82 (88.1%) were submitted to videolaparocholecystectomy (VLC); in 11 (11.8%) cases, not eligible for endoscopic therapy to remove stones, open cholecystectomy and choledocholithotomy were programmed. We have compared our results of two stage laparoscopic-endoscopic procedure with the results of one stage laparoscopic endoscopic management and laparoscopic approach alone (from the literature). We also evaluated the distant results of sphincterotomy in 58 patients after 6 and 12 months with clinical, bioumoral and instrumental follow-ups.

Results

The results of statistical analysis for predictive tests of choledocholithiasis have been well defined (Tables I, II) Univariate analysis has identified as predictive factor of choledocholithiasis alkaline phosphatase, gamma-GT, direct bilirubin and a dilatation greater than 8 mm of

TABLE I - *Bio umoral/instrumental tests predictive of choledocholithiasis*

N=35	AST (U/L)	ALT (U/L)	Alkaline Phosphatase (U/L)	Gamma-GT (U/L)
Cut-off (normal less than the indicated value)	40 U/L p = 0.3307	40 U/L p = 0.3399	136 U/L p < 0.0001	200 U/L p < 0.0001

N=35	Total Bilirubin (mg/dL)	Conjugated Bilirubin (mg/dL)	Pancreatic Amylase (U/L)	Lipase (U/L)	PBD dilatation on USG (mm)
Cut-off (normal less than the indicated value)	1.2 mg/dL p = 0.078	0.4 mg/dL p < 0.0001	52 U/L p = 0.4444	255 U/L p = 0.4921	8 mm p < 0.0001

Univariate Analysis (Exact Fisher Test - 95 % confidence interval)

TABLE II - *Bio umoral/instrumental tests predictive of choledocholithiasis*

N=35	AST (U/L)	ALT (U/L)	Alkaline Phosphatase (U/L)	Gamma-GT (U/L)
Cut-off (normal less than the indicated value)	40 U/L p = 0.2801	40 U/L p = 0.5892	136 U/L p < 0.0001	200 U/L p < 0.0001

N=35	Total Bilirubin (mg/dL)	Conjugated Bilirubin (mg/dL)	Pancreatic Amylase (U/L)	Lipase (U/L)	PBD dilatation on USG (mm)
Cut-off (normal less than the indicated value)	1.2 mg/dL p = 0.085	0.4 mg/dL p < 0.0001	52 U/L p = 0.5892	255 U/L p = 0.263	8 mm p < 0.0759

Multivariate Analysis (Exact Fisher Test - 95 % confidence interval)

the CBD ($p < 0.0001$). AST, ALT, lipase and amylase instead have not shown predictive value of cholestasis. Also, alkaline phosphatase, gamma-GT and direct bilirubin have turned out to be independent predictive factors of choledocholithiasis in the multivariate analysis. On the contrary, AST, ALT, dilatation of the CBD by US, lipase and amylase have not shown statistical significance. Choledocholithiasis has been confirmed by ERCP in all patients (93/93 - 100%) either in those with diagnostic certainty before surgery and in the others with suspicion of choledocholithiasis. Endoscopic removal of stones and cleansing of the biliary duct have been performed in 82 patients (88,17%); in 13 cases (13,97%) it has been necessary to repeat the procedure. On the contrary 11 patients (11,82%) were not eligible for endoscopic approach because of the size and location of the stones; therefore, these patients have been submitted to laparotomic therapy. The results of the treatment of 93 choledocholithiasis are summarized in Table III.

Minor morbidity turned out to be contained (port-site infections, umbilical hernias, etc); surgery time, hospital stay and resumption of alimentation are overlapping with data from literature. The greater morbidity relative and specific to ERCP/ES is defined overall as 5% and is represented by duodenal perforation, severe pancreatitis and bleeding. Duodenal perforation in a patient has been treated with surgical therapy (always derivative) while in one case it has been possible to adopt a conservative medical therapy. The case of severe acute pancreatitis has been successfully treated with medical therapy. Also bleeding showed self limiting evolution with medical and

TABLE III - *Choledocholithiasis / sequential therapy*

ERCP/ES- VLC 93 patients	
Results	
Diagnosis	93/93 – 100%
Success rate –endoscopic therapy	82/93 (88.17%)
Mean LC operative time	50' ± 25'
Mean hospital stay (post ERCP/ES-VLC)	9 days
Resumption of alimentation	4 days
Umbelical port-side infection	7/93 (7.5%)
Umbelical hernias	2/93 (2.15%)
Major morbidity	
Duodenal perforation	2/93 (2.15%)
Severe acute pancreatitis	2/93 (2.15%)
Bleeding	1/93 (1.07%)
Cholangitis	-----
} 5,37%	
Minor morbidity	
Hyperamylasemia (mild acute pancreatitis)	8/93 (8.6%)

endoscopic approach. Among minor complications of ERCP/ES we mention mild pancreatitis with only evident amylase increase, characterized by fast spontaneous resolution. Review of the literature allows a comparison of the results between the mini-invasive procedures: two stage transpapillary endoscopic access with ERCP/ES and stones removal before VLC or one stage with LaparoEndoscopic Rendez Vous technique (LERV)/VLC and laparoscopic approach, IOC - trans-cystic stones removal or by choledochotomy during VLC. The aim of this comparison is firstly to evaluate the differences between the different approaches in terms of major or minor morbidity and of success in the removal of stones in the CBD. Secondly to consider the surgery time, comfort and post-surgery recovery and in sum the hospital stay (Table IV). In 58 patients out of 93 who had undergone ERCP/ES (62.4%), we have evaluated after 6 and 12 months (until December 2010) the appearance of symptoms related to obstacle to biliopancreatic flow, because of papillary inflammatory stenosis from anomalous evolution of the scar after ES (and transpapillary maneuvers). The clinical picture can be assimilated to the dysfunction of the sphincter of Oddi¹⁶. The appearance of painful symptomatology possibly related to “biliary colic” (medium intensity pain of colic type to the right hypochondrium or to the epigastrium sometimes radiating to the back without temporal cadence, not influenced by posture or emission of gas and stool), the increase of hepatic enzymes (AST, ALT), of alkaline phosphatase (ALP) and bilirubin, and lastly the diameter of CBD by US, have been assessed. These follow-ups have shown symptoms related to ES (colic pain to the right hypochondrium with mild increase of blood indexes of cholestasis without dilatation of CBD) only in two cases (2,4%) at the first follow-up (6 months). The biliary

TABLE IV - *Comparison between mininvasive procedures*

	VLC+IOC+laparoscopic choledocholitotomy	ERCP/ES + VLC	LERV
Success rate of the procedure	90% (85%-95%)	92.2% (86%-95.6)	84% (61%-95.5%)
Conversion rate	5.8%	-----	-----
Mean operative time	120' ± 40'	60' ± 30'	45' ± 20'
Mean recovery time	7 days	9 days	7 days
Lithiasis recurrence	6.7%	7%	=
Morbidity rate	8.8%	4%	=
Mortality	0.7%	0.8%	=
Bile leak		2%	=
Collection/biloma		2%	=
Pancreatitis		2%	=
Hyperamylasemia		10%	
References	1,2,3,4	5,6,7,8,9,10 personal data	11,12,13,14,15

colic pain and the bioumoral alterations without dilatation of the bile duct were resolved quickly with medical therapy. The successive follow-ups (12 months) have been negative in all the patients.

Discussion

Cholecystocholedocholithiasis (or residual choledocholithiasis in patients who underwent cholecystectomy) can manifest itself with a perfectly clear and definite clinical, instrumental and bioumoral picture, or be only a suspicion. The history and natural evolution of choledocholithiasis shows that in a certain number of patients with gallbladder lithiasis, choledocholithiasis is completely asymptomatic. The frequency of asymptomatic choledocholithiasis in patients who underwent cholecystectomy varies between 5 and 15%^{5,17}, and it is also possible that in approximately 1/3 of the cases choledochal stones move spontaneously into the duodenum within an average period of six weeks. The rationale of our therapeutic program is based on two objectives: complete preoperative diagnosis by means of non invasive clinical-instrumental examinations and treatment with mini-invasive approach. These diagnostic-therapeutic choices are object of a wide and articulated discussion. We think useful, safe and reliable to complete the preoperative diagnosis of CBD lithiasis on the basis of the availability of non invasive instrumental examinations. Trans-abdominal US, endoscopic US, MRCP and CT are to be considered. Trans-abdominal US is the first choice when suspecting choledocholithiasis with 95% specificity and 25-63% sensibility¹⁸ conditioned by the experience of the examiner. Endoscopic US offers better performances

with approximately 95% sensibility and 95-98% specificity¹⁹. However, the procedure cannot be considered completely non invasive and heavily relies on the experience of the examiner. MRCP is widely predominant for its performances among preoperative exams: sensibility and specificity vary between 95 and 97% in detecting choledocholithiasis²⁰. CT offers analogous diagnostic possibilities²¹. Basic clinical, laboratory and instrumental data (trans-abdominal US), integrated by MRCP allow to select the patients with founded probability of CBD lithiasis which are destined to ERCP/ES for diagnostic confirmation and relevant treatment. On the other hand intraoperative cholangiography (IOC), like other preoperative exams (endoscopic US, MRCP), is performed in patients submitted to cholecystectomy in whom choledocholithiasis is suspected on the basis of clinical-laboratory-instrumental criteria. IOC can be executed either with laparoscopic or open approach and the access is nearly always transcystic. IOC sensibility is 98% while specificity is 94%^{22,23}. In our opinion IOC can demand invasive maneuvers on the biliary duct because of the difficulty or impossibility to cannulate the cystic duct. Sometimes choledocholithotomy, also with laparoscopic approach, is necessary after which it may follow the possibility (or necessity) of draining the biliary duct (T tube, transcystic drainage). Moreover IOC shows a not negligible number of false positives reaching 20-25% for transcystic access²⁴ and of uncertain results for outflow of contrast medium during the exam, air bubbles, too quick transit into the duodenum, spasm of the sphincter of Oddi. Choledocholithiasis treatment procedures can nowadays be summarized in three possibilities: two-stage endoscopic/laparoscopic/ERCP sequential approach, sphincterotomy and CBD clearance followed after 48 hours by laparoscopic cholecystectomy. In the same endoscopic field the one stage approach with LERV technique (lap cholecystectomy and ERCP/ES for clearance of CBD). Finally the one stage totally laparoscopic treatment: cholecystectomy, stones removal through cystic duct or choledocolitotomy.

With the ERCP/ES sequential procedure followed 48 hours later by VLC the percentage of success for the cleaning of the biliary tract varies between 61% and 95.5%, but in approximately 1/4 of the cases it is however necessary to repeat the procedure twice or more²⁵⁻²⁷. Moreover total morbidity of one and two stage laparoscopic procedure must be mentioned, oscillating around 5-11%^{25,28}. In particular the morbidity of ERCP/ES is represented by transitory serum amylase increase, pancreatitis, hemorrhage, perforation^{29,30}. Mortality is absent or reaches 0,7%. It must not be forgotten that sometimes this procedure can not be performed because of "impossibility to access the papilla", voluminous or compacted stones or anatomical difficulties of finding (for example reconstructions after gastric resection) (11,84% of cases in our experience).

Success rate of laparoscopic exploration of bile duct by means of IOC to remove stones varies between 85 and 95%, with morbidity between 4-16% and mortality between 0-2%^{1,2}. The procedure can be performed with transcystic extraction of stones or it may be necessary to perform choledocholithotomy. Moreover it is possible to resort to balloon dilatation of the cystic duct and to use of choledochoscopy. As a result of choledochotomy, in order to avoid even minimal post-operative cholerrhagias, it is useful to drain the biliary duct with T tube or with transcystic drainage. The drainage must be removed after 3-4 weeks. It involves an effective reduction of possible cholerrhagias and allows an ulterior contrastographic control before the removal, but it is accompanied by the danger of scar stenosis in normal or small-caliber bile ducts. The result of the comparison among these procedures shows a substantial equivalence³¹. Moreover recent studies have shown statistically non significant differences also in the comparison between the results of one and two stage endoscopic/laparoscopic approaches. A particular consideration should be addressed to the exploration and laparoscopic treatment alone of cholecystocholeolithiasis. This procedure did not find wide and uniform diffusion in the surgery community. It has remained confined to centers with great experience in laparoscopy. Moreover, in our opinion, some elements limit its indication: difficulties in transcystic passage of stones, choledochotomy of a narrow biliary way, impacted stones, etc. In conclusion the diffusion of endoscopic or laparoscopic procedures for the exploration of the biliary way has a rather variable progress and is predominantly connected to the prevalence of the specific endoscopic or laparoscopic competencies in the hospital where the patient is treated. In sum, preoperative ERCP/ES with CBD cleaning followed by VLC remains the strategy more frequently applied in clinical practice, notwithstanding the good results of laparoscopic approach^{6,32-34}. Endoscopic treatment has remained the treatment of reference and comparison in all the clinical evaluations of the different procedures proposed³⁵. Moreover choledocholithiasis, in which transpapillary passage of little stones or cholesterol crystals frequently occurs, can be cause of sclerosis of the sphincter of Oddi. Sclerosis of the sphincter of Oddi and papillary sclerosis constitute the physiopathological basis of recurrent biliary acute pancreatitis because of the persistence of the papillary obstacle. Therefore in patients with choledocholithiasis, transpapillary endoscopic access with sphincterotomy and extraction of stones can represent an effective prevention of recurrent biliary pancreatitis. Finally, open access with classic choledocholithotomy is, in our opinion, still to be numbered among the possible therapeutic solutions, even if with ever increasing limited employment, and it remains the final choice when the expected result has not been achieved with other procedures.

Conclusions

The diagnostic-therapeutic program of cholecystocholedocolithiasis is decidedly oriented towards mini-invasive procedures in which various modalities of approach exist³⁶. The results of the sequential procedure ERCP/ES + stones removal + VLC or one stage LERV^{11,12,37,38} and VLC + IOC + laparoscopic choledocholithotomy^{6,31-34} overlap. Therefore the choice between these modalities is widely conditioned by the background of the surgical team (opinions, convictions, repetition and standardization of the procedures), by the well established technical skills and lastly by the results which, in every experience are true and objective but conditioned by and partially connected to the characteristics of the group which achieves them. Our preference is clearly directed to the objective of having a high probability preoperative diagnosis of choledocholithiasis with clinical and laboratory methods and non invasive instrumental exams (trans-abdominal US - MRCP). In the therapeutic phase we prefer the endoscopic trans-papillary approach for its high rate of success and contained morbidity. This procedure is favoured by the high frequency of small and moving stones. Lastly, it eliminates all maneuvers on little size bile ducts with normal walls. Finally endoscopic sphincterotomy, allowing the resolution of the possible and probably papillary sclerosis/stenosis in the patients with cholecystocholedocol stones, can be useful in the prevention of recurrent pancreatitis.

Riassunto

INTRODUZIONE: Il trattamento della coledocolitiasi è stato rivisitato nell'ambito dell'approccio mini-invasivo sia endoscopico che laparoscopico. Una procedura diagnostico-terapeutica standardizzata non è ancora unanimemente condivisa.

PAZIENTI E METODI: Durante il periodo 1997-2011 abbiamo trattato 924 pazienti: 555 coledocolitiasi, 276 pancreatiti acute biliari e 93 coledocolitiasi senza pancreatite. Abbiamo valutato, sulla base dei dati della letteratura, i nostri risultati dell'approccio sequenziale di rimozione endoscopica dei calcoli e successiva colecistectomia laparoscopica rispetto all'approccio endoscopico-laparoscopico in un tempo (rendez-vous technique) e all'approccio totalmente laparoscopico.

RISULTATI: Nella nostra esperienza la rimozione dei calcoli per endoscopica è stata ottenuta in 82 pazienti (88.17%); mentre 11 pazienti (11.82%), per i quali non è stato possibile il trattamento endoscopico, sono stati trattati per via laparotomica. In sintesi la bonifica preoperatoria della via biliare principale tramite ERCP/ES e successiva VLC, nonostante i pur validi risultati ottenuti dall'approccio laparoscopico, rimane la strategia più frequentemente applicata in campo clinico per via dei buoni risultati.

CONCLUSIONI: I risultati del trattamento della coledocolitiasi con approccio sequenziale endoscopico-laparoscopico (in due o unico tempo) e con approccio solo laparoscopico sono sostanzialmente sovrapponibili.

Comunque la prima procedura rimane il trattamento di scelta e il metro di riferimento nei confronti di altre procedure cliniche adottabili.

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