

• BRIEF REPORTS •

Predictors of common bile duct lithiasis in laparoscopic era

George Sgourakis, Georgia Dedemadi, Athanasios Stamatelopoulos, Emmanuel Leandros, Dionysius Voros, Konstantinos Karaliotas

George Sgourakis, Georgia Dedemadi, Athanasios Stamatelopoulos, Emmanuel Leandros, Dionysius Voros, Konstantinos Karaliotas, 2nd Surgical Department of Korgialenio-Mpenakio Red Cross Hospital, Athens, Greece; Surgical Department of Hippocraton, University Hospital of Athens, Greece; Surgical Department of Areteion, University Hospital of Athens, Greece

Correspondence to: George Sgourakis, MD, PhD, 11 Mantzarou str., Neo Psychiko, 15451 Athens, Greece. gsgourakis@hotmail.com
Telephone: +30-210-6716015

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Abstract

AIM: To analyze retrospectively the records of 294 consecutive patients operated upon for gallbladder stones, to determine the predictive factors of synchronous common bile duct (CBD) stones and validate prospectively the generated model.

METHODS: The prognostic estimation of a biochemical test and ultrasonography alone to differentiate between the absence and presence of choledocholithiasis was assessed using receiver operating characteristics curve analysis. Multivariate analysis was employed using discriminant analysis for establishment of a best model. Prospective validation of the model was made.

RESULTS: Discriminant forward stepwise analysis disclosed that high values ($\geq 2 \times$ normal) of SGOT, ALP, conjugated bilirubin and CBD diameter on ultrasound ≥ 10 mm were all prognostic factors of CBD lithiasis in univariate and multivariate analysis, $P < 0.01$. History was not included in the model. Prospective validation of the model was performed by multivariate analysis using Visual General Stepwise Regression. Positive predictive value, when considering all these predictors, was 93.3%, while the negative predictive value was 88.8%. Sensitivity of the model was 96.5% and specificity 80%.

CONCLUSION: The above model can be objectively applied to predict the presence of CBD stones.

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Key words: CBD lithiasis; Predictors of CBD stones; Laparoscopic CBD exploration

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INTRODUCTION

Evolving laparoscopic techniques of common bile duct (CBD) exploration aroused interest on the debate of the optimal management of patients with suspected CBD stones, who underwent laparoscopic cholecystectomy. CBD stones are present in 10-15% of patients, though the incidence declines in recent years after the widespread acceptance of laparoscopic cholecystectomy. Further inquiry of the usefulness of CBD stone predictors is, therefore, highly necessary. The records of 294 consecutive patients operated upon laparoscopically for gallbladder stones from June 1993 until June 1994 were taken into analysis retrospectively.

Forty-two patients were documented to have CBD lithiasis, based on the data of intraoperative cholangiography, which was technically feasible in 263 patients.

An optimal model if CBD stone prediction was established based on these data and validated prospectively by Visual General Stepwise Regression (VGSR) in a subsequent series of patients undergoing laparoscopic cholecystectomy.

MATERIALS AND METHODS

All patients admitted for extrahepatic biliary tree pathology, were evaluated with ultrasonography and liver enzyme profile in addition to a detailed history. Enrollment to this study was strictly limited to the patients who fulfilled at least one of the prognostic factors for CBD lithiasis found in a preliminary retrospective study.

The records of 294 consecutive patients operated upon laparoscopically for gallbladder stones from June 1993 to June 1994 were taken into analysis retrospectively.

Among the 294 patients, only 280 had a complete record with detailed histories (present and past), ultrasound, liver enzyme profile at admission (except for γ GT and SGPT) and intraoperative cholangiography. Biochemical results were considered abnormal for a patient with any of the followings: direct bilirubin > 1 mg/100 mL, alkaline phosphatase > 300 U/L, alanine aminotransferase > 35 U/L. Dilatation of CBD was considered if a diameter of > 6 mm was measured in its midportion. The suspicion of presence of CBD stones seen on ultrasound was also recorded.

Forty-two patients (14%) were documented to have CBD lithiasis according to the data of intraoperative cholangiography which was technically feasible in 263 (94%) patients.

Predictors of CBD lithiasis were defined for better patient selection in a prospective randomized trial comparing laparoscopic CBD exploration and cholecystectomy *vs* ERCP, endoscopic sphincterotomy and laparoscopic cholecystectomy^[1].

From April 1997 to August 2000, all the patients presented with, at least one of the predictors, as dictated by the preliminary

retrospective study were enrolled in the protocol. Excluded from the study were patients:

- With physical status ASA \geq III
- Who did not sign the informed consent
- Who had past abdominal procedures which should exclude laparoscopy
- Suffering from malignancy or other pathology, affecting life expectancy
- With recurrence of CBD lithiasis
- Who had to be operated upon for concurrent pathology
- With coagulation disorders
- Presented with multiple intrahepatic lithiasis
- Who had concurrent pathology of the extrahepatic biliary tree (fistulas, choledochal cysts, *etc.*).

The remaining patients were assigned into two groups (laparoscopic CBD exploration, group A and combined approach, group B), by opening a sealed envelope. The time interval between the onset of acute symptoms and intervention was 24-48 h.

Demographic characteristics, mean values and standard deviations of liver function tests and ultrasonographic findings of the 78 patients are depicted in Tables 1-3, respectively.

After confirming CBD lithiasis with intraoperative cholangiography, patients of group A were addressed laparoscopically, either with direct CBD exploration or with transcystic duct stone extraction and cholecystectomy. Patients of group B were referred for ERCP and potential ES and stone extraction through the ampulla, and laparoscopic cholecystectomy was done later (24 or 48 h).

Table 1 Clinicopathologic characteristics of patients of both groups

	Group A	Group B
Number	36	42
Female	21	25
Male	15	17
Age (yr)	43-88	46-89
Positive history		
Fever	3	3
Jaundice	8	9
Chills	1	1
Pancreatitis	1	1
Total	13	14
Ultrasonographic CBD diameter \geq 10 mm	33	37
SGOT \geq 2 normal	21	26
dBil \geq 2 normal	15	17
ALP \geq 2 normal	18	22

Table 2 Mean values and standard deviation of liver function tests

	Group A	Group B
SGOT		
Mean	197 U/L	189 U/L
Standard deviation	38 U/L	35 U/L
Bilirubin		
Mean	5.2 mg/100 mL	4.1 mg/100 mL
Standard deviation	2.2 mg/100 mL	1.8 mg/100 mL
ALP		
Mean	540 U/L	469 U/L
Standard deviation	87 U/L	81 U/L

Table 3 Ultrasonographic findings

	Group A	Group B
CBD diameter <10	3	5
CBD diameter ≥ 10	33	37
CBD diameter		
Median	10.5	11
Range	5-21	5-23
Choledocholithiasis		
Positive	11	14
Suspected	18	21

Laparoscopic direct common bile duct exploration^[2-5]

Selection of the flexible choledochoscope was made between one of the medium size (10 Fr, 3.3 mm) and the other of the large size (15 Fr, 5.5 mm). The small size choledochoscopes are not proper for this method because of inefficient vision, inadequate lavage facilities and the need for large baskets for sizable stone pick up.

The rest of the equipment included 30° laparoscope, curved pair of scissors, knife, a Semm forceps, irrigation-suction device, and a pair of laparoscopic needle holders (alternatively an endostitch apparatus). CBD suturing was made by 4/0 coated vicryl or 4/0 polysorb threads.

In addition to the classical sites of port placement in laparoscopic cholecystectomy, a fifth 11 mm port was put at right of the midline (in the immediate proximity) to the xiphoid for the insertion of the choledochoscope and cholangiography was performed.

It was important that the continuity of the cystic duct with both the CBD and the gall bladder was maintained since this enables fixation of the CBD by lateral and upward traction of the gall bladder. After that, we were able to proceed to the anterior dissection of the supraduodenal segment of the CBD in about a 2-cm long and 1-cm wide area, while the duodenal bulb was mobilized downward. Mobilization of hepatic artery or its right branch is necessary if these entities cross the bile duct in this region.

Choledochotomy procedure: the opening should not exceed 1.0 cm at first instance. External massage and manipulations of the lower bile duct is surprisingly efficacious and should always be tried as the first measure. After that, a biliary balloon catheter was inserted through the subxiphoid port into the bile duct. Blind biliary balloon stone dislodgment was successful in some of our patients. Smaller stones can also be removed using the sucker tip.

Visually guided extraction with the flexible choledochoscope by wire baskets or long balloon catheters of Fogarty type was successful in the vast majority of our patients. Upon completion of the procedure, the entire biliary tract (proximal and distal) was inspected and shown to be free of calculi and debris and a cholangiogram was also done to ensure complete duct clearance.

Drainage of the extrahepatic biliary tree was done through a T-tube insertion or through the cystic duct stump with primary closure of the bile duct. Closure is accomplished with interrupted 4/0 absorbable sutures. After cholecystectomy, a subhepatic drain was inserted.

Cholangiography was performed on the 8th postoperative day and the T-tube or the cystic duct cannula was removed 2 d later.

Laparoscopic transcystic duct exploration^[6]

Flexible choledochoscope must have an outside diameter of no larger than 3 mm.

Not infrequently, the duct was cleared before the scope had been completely prepared by noncholedochoscopic maneuvers such as pharmacologic relaxation of the sphincter of Oddi, administration of 1-2 mg of intravenous glucagon, flushing of the cholangiocatheters with saline, balloon and helical or straight basket techniques.

Three tools are available to dilate the cystic duct for choledochoscope entry: curved forceps, mechanical graduated dilators and pneumatic high pressure balloon dilators. The choledochoscope was inserted through the midclavicular port into the cystic duct. Choledochoscopic stone retrieval was most commonly achieved using a basket inserted through the channel of the scope.

Balloon-tipped catheters were also used. These catheters generally do not fit in the working channel of the newer small-diameter scopes, so they must be inserted adjacent to the scope. In cases that scope or stone passage was not feasible, the cystic duct wall was cut longitudinally towards the common duct. If the incision included or abut the cystic duct-CBD junction, some stitches were sewn. Most often this was accomplished without the placement of a T-tube unless there was a good reason for doing so.

Patients were followed every 3 mo by phone and every 6 mo by personal conference and if mandatory, laboratory tests and ultrasonography were prescribed. There were no violations of the protocol.

Statistical analysis

The corresponding proportion and total number of patients were expressed for each clinical predictor. When distributed normally, continuous variables were described using mean and standard deviation, if not they were expressed as median and range. All parameters were analyzed as categorical variables.

A sensitivity analysis of all possible predictors was conducted through an ST Neural Network. The prognostic estimation of a biochemical test alone to differentiate between the absence and presence of choledocholithiasis was assessed using receiver operating characteristics (ROC) curve analysis. For each test, one cut-off value was chosen by determining the point closest to an ideal test with 100% specificity and sensitivity (the upper most left corner of the graph).

Discriminant forward stepwise analysis, using the ideal cut-offs determined at ROC curve analysis, was employed to retrospective data to establish the model that could best predict the presence of a CBD stone. Positive and negative predictive values were determined for all predictors. Prospective validation of the model that predicts choledocholithiasis was done by VGSR. In addition, the parameter coefficients of the initial model were compared with those obtained from the data of the prospective study.

Statistical analysis was made using the Statistica (StatSoft) software. Results with *P* values less than 0.05 were considered to be statistically significant.

RESULTS

Retrospective study

Eight potential prognostic factors (positive history, past and

present; abnormal values of LDH; amylase; SGOT; dBil; ALP and CBD diameter on ultrasound) were considered for evaluation as predictors of choledocholithiasis. A sensitivity analysis was conducted through an ST Neural Network. Variables pruned because of training, and verification ratios below the threshold were: past history, amylase and lactate dehydrogenase, and were removed from the underdevelopment model of predictors. The "rank" on sensitivity datasheet was CBD diameter = 1, ALP = 2, dBil = 3, SGOT = 4. The best network found had good performance: correct classification rate 0.894737 and area under ROC curve 0.946328. ROC curve was used to select an optimum decision threshold (value that equalizes the probability of this classification of either class of false positive and false negative). Diameter of the supraduodenal CBD documented by ultrasonography was categorized into two cut-off values: >6 and ≥ 10 cm. The ideal cut-off was 10 mm. History was categorized as positive (presence of fever, jaundice, chills, pancreatitis) or negative. Categorical classification of liver enzymes was done by two values: simply elevated and equal or above twice normal. The ideal cut-off value was twice as normal.

In 42 patients with choledocholithiasis, positive histories were present in 36%, CBD diameter ≥ 10 mm on ultrasound in 95% and more or equal twice normal values of SGOT in 59%, dBil in 42%, and ALP in 50%. In the remaining 238 patients without evidence of CBD lithiasis in intraoperative cholangiography, positive histories were present in 5%, CBD diameter ≥ 10 mm in 15% and more or equal twice normal values of SGOT in 11%, dBil in 7% and ALP in 7%.

Discriminant forward stepwise analysis disclosed that high values ($\geq 2 \times$ normal) of SGOT, ALP, conjugated bilirubin and CBD diameter on ultrasound ≥ 10 mm were all prognostic factors of CBD lithiasis in univariate and multivariate analysis at a level of $P < 0.01$. History was not included in the model.

Positive predictive value (PPV), when considering all predictors was 93%, while the negative predictive value (NPV) was 95%.

Prospective study

From April 1997 to August 2000, 97 patients fulfilled the criteria of enrollment in the protocol as dictated by the preliminary retrospective study.

The following 19 patients were excluded from the study:

- Physical status \geq ASA III (seven patients)
- Did not sign the informed consent (six patients)
- Past procedures which should exclude laparoscopy (two patients)
- Recurrence of CBD lithiasis (one patient)
- Huge esophageal hernia (one patient)
- Von Willebrand disease (one patient)
- Choledochal cyst (one patient).

There were no statistically significant differences regarding demographic and clinicopathological characteristics, ultrasonography and liver function tests among patients of both groups (Mann-Whitney *U* test was applied). Postoperative follow-up was made for 7-36 mo (median 22.36 mo).

Group A: Twenty-eight of thirty-six patients of group A had CBD lithiasis, 12 patients had direct CBD exploration and, the transcystic duct approach was applied in the remaining 16.

The application of direct CBD exploration was unsuccessful in three patients: there was conversion to open in one patient and the rest two patients were referred for endoscopic stone extraction. We had only one failure in the application of the transcystic duct approach and the patient was also referred for endoscopy.

The median duration of laparoscopic CBD exploration was 90 min (range 70-310 min). Median hospital stay was 7.4 d (5 d for transcystic duct approach and 11 d for direct CBD exploration).

Group B: Thirty-two of forty-two patients of group B had CBD lithiasis. In five patients, endoscopic stone extraction was unsuccessful and all were referred for open choledochotomy. Median hospital stay was 9 d. Duration of ERCP and ES in addition to the time spent for LC was 60-255 min (median 105 min).

The short-and long-term results from the application of the above-mentioned laparoscopic and endoscopic procedures are shown in Table 4.

Table 4 Short and long term results

	Group A	Group B
Number of patients	36	42
Patients with CBD lithiasis	28 (1 ¹ , 16 ²)	32
Successful stone extraction	24/28 (85.7%)	27/32 (84.3%)
Method failure	4/28 (14.3%)	5/32 (15.7%)
Conversion to other procedure	4/28 (14.3%)	5/32 (15.7%)
Total morbidity	5/28 (17.8%)	6/32 (18.7%)
Death	1 ³	1 ⁴
Mean hospital stay (d)	7, 4 (5 ² , 11 ¹)	9
Stones remaining during follow up	1	1
CBD stenosis	0	1

¹Direct CBD exploration. ²Truncystic duct CBD exploration. ³On the 40th postoperative day at home. ⁴Acute myocardial infarction 2 d after endoscopy.

Table 5 Complications

	Group A	Group B
Cholangitis	0	1
Mild pancreatitis	0	2
Bile collection	0	1
Biliary fistula	1 ¹	0
Pulmonary embolism	1	0
Death	1 ²	1 ³
Sepsis	0	1
Abdominal wall hematoma	2	0
Upper G.I. hemorrhage	0	1
Cardiovascular	1	0

¹After direct CBD exploration. ²On 40th postoperative day at home. ³Acute myocardial infarction 2 d after endoscopy.

Complications encountered among patients of both groups are depicted in Table 5.

Rank sum test disclosed that there was not a statistically significant difference among patients of both groups concerning morbidity ($P = 0.87$), mortality ($P = 0.70$) and hospital stay ($P = 0.07$). On the contrary, there was statistically significant difference regarding hospital stay in favor of patients that underwent the transcystic duct approach ($P < 0.01$).

To compare long-term results, we applied the Gehan's Wilcoxon test but a statistically significant difference was not found ($P = 0.70$).

Prospective validation of multivariate model

In order to validate prospectively the multivariate model, we used the VGSR module to build a model for our design with multiple degrees of freedom effects for categorical predictor variables.

The best model for predicting bile duct stones included the following independent predictors: CBD diameter ≥ 10 mm (dichotomized, using a cut-off value of 10 mm) and elevated values (≥ 2 normal) of SGOT, dBil, ALP (dichotomized using a cut-off value of equal to twice normal).

All the above were predictors on univariate analysis even after using the Bonferroni-Holm method to adjust for multiple comparisons. Level of significance in univariate analysis for CBD diameter ≥ 10 mm, and elevated values (≥ 2 normal) of SGOT, dBil, ALP was $P < 0.01$ for each of them. Table 6 shows the performance of each possible predictor of CBD lithiasis analyzed including positive and NPVs. Table 7 depicts the model building via forward stepwise regression.

There were no significant differences between observed and predicted probabilities in the subgroups of patients when broken down according to the different possible predictor combinations.

The respective coefficients for each of the predictors were: CBD diameter ≥ 10 mm (0.314982024), SGOT (0.227198578), dBil (0.244231286), ALP (0.207177395).

Prediction equation for choledocholithiasis was: CBD lithiasis = $-0.03912693 + 0.314982024 \times \text{CBD} \geq 10 \text{ mm} + 0.227198578 \times \text{SGOT} + 0.244231286 \times \text{dBil} + 0.207177395 \times \text{ALP}$ in which CBD diameter $\geq 10 = 1$ if yes or $= 2$ and if not, values of SGOT, dBil, ALP = 1 if ≥ 2 normal or 2 if lower. Presence of CBD stone in a given case, is to be expected if the result of the equation is ≤ 1.5 , the opposite is true if the result is > 1.5 . Consequently, parameter coefficients of the model did not vary significantly when retrospective and prospective data were combined. PPV, when considering all these predictors, was 93.3%, while the NPV was 88.8%. Sensitivity of the model was 96.5% and specificity 80%.

Table 6 Performance of predictors in univariate analysis

Predictor	Number of patients (%)	PPV (%)	NPV (%)
CBD ≥ 10 mm	70/78 (89.7)	74	87.5
SGOT ≥ 2 normal	32/78 (41)	46	97
dBil ≥ 2 normal	33/78 (42.3)	48	97
ALP ≥ 2 normal	40/78 (51.2)	42	95

DISCUSSION

Laparoscopic cholecystectomy and evolving laparoscopic techniques of CBD exploration renewed interest on the debate of the optimal management of patients with suspected CBD stones who underwent cholecystectomy^[7,8].

Table 7 Building the model via forward stepwise regression

Summary of stepwise regression; variable: lithiasis. Forward stepwise <i>P</i> to enter: 0.05, <i>P</i> to remove: 0.05							
	Steps	Degrees of freedom	<i>F</i> to remove	<i>P</i> to remove	<i>F</i> to enter	<i>P</i> to enter	Effect status
History	Step 1	1			0.18442	0.6688	Out
CBD_10		1			15.9619	0.0001	Out
SGOT		1			48.4107	1.05E-09	Out
Bil		1			63.4082	1.3E-11	Entered
ALP		1			55.3074	1.31E-10	Out
Bil	Step 2	1	63.4082	1.29624E-11			In
CBD_10		1			10.6347	0.0016	Entered
SGOT		1			9.16433	0.0033	Out
History		1			3.33518	0.0717	Out
ALP		1			7.98087	0.0060	Out
Bil	Step 3	1	54.81658	1.61316E-10			In
CBD_10		1	10.6347	0.0016709			In
SGOT		1			8.23132	0.0053	Entered
History		1			0.31224	0.5779	Out
ALP		1			6.52043	0.0127	Out
Bil	Step 4	1	17.77605	6.94475E-05			In
CBD_10		1	9.667935	0.0026617			In
SGOT		1	8.231323	0.0053630			In
History		1			0.39927	0.5294	Out
ALP		1			4.50211	0.0372	Entered
Bil	Step 5	1	5.631729	0.0202726			In
CBD_10		1	8.529480	0.0046459			In
SGOT		1	6.148871	0.0154574			In
ALP		1	4.502116	0.0372471			In
History		1			0.62724	0.4309	Out

CBD stones are present in 10-15% of patients undergoing cholecystectomy^[9] though the incidence declines in recent years after the widespread acceptance of LC, possibly due to earlier presentation in the natural course of symptomatic gallstone disease.

Criteria for selective endoscopic cholangiography or intraoperative cholangiography before LC have not been adequately defined.

Laparoscopic CBD exploration poses doubt about the effectiveness of ES in CBD clearance and its potential advantages in terms of morbidity or mortality. Several strategies have emerged to manage synchronous CBD stones: i.e., open CBDE, laparoscopic CBDE or postoperative ERCP with stone extraction. An inadvertently discovered CBD stone at the time of LC has to be addressed laparoscopically if this technique is mastered by the surgeon, otherwise posing the dilemma between converting to an open procedure or relying on postoperative ERCP for stone retrieval.

Routine preoperative cholangiography and sphincterotomy in the presence of stones is not a cost-effective prospective, taking also into account the relevant morbidity of 5-10% and mortality rate of 1-3%^[9]. Intraoperative cholangiography is successful in 88% of patients, who have a PPV of 63-92%^[10], delineates the intra- and extra-hepatic biliary anatomy and potentially prevents bile duct injury. Routine use of IOC lengthens the operative time and has a sizable false positive rate ranging from 21% to 67%, which should obviate unnecessary CBD exploration or conversion to open surgery.

In a public institution with limited resources, a choice should be made to limit the number of negative ERCs, and IOCs is mandatory. It is well known that the higher the increase of liver function tests, the increase in patients who

have CBD stones. Although ultrasonography could produce a good chance of prediction, a dilated CBD alone is an unreliable indicator. Combination of CBD diameter with high values of LFT, increases its PPV, perhaps by reflecting ongoing biliary obstruction^[11].

We believe that the high percentage of CBD lithiasis among those patients is due to the fact that the vast majority of admissions were on an emergency basis as well as that the socioeconomic status of the major area is low.

Strengths of the present study lie in the use of:

- ST Neural Network to avoid a poorly adapted statistical technique with highly intercorrelated clinical predictors. LDH, amylase and past history were removed from the model. Increased levels of serum amylase and a history of pancreatitis according to bibliography are not significant predictors of a CBD stone^[11,12]. Clinical practice suggests that unsustained increase of serum amylase reflects recent stone passage across the sphincter of Oddi.
- ROC curve analysis for optimal prediction of serum liver function tests and ultrasonographic CBD-diameter, cut off values.
- Multivariate model and the assessment of homogenous population in terms of enrollment in a randomized trial protocol, avoiding inclusion of patients with retained or recurrent stones because such a population subset has a different biological behavior.
- A relatively long follow-up, which can prevent in part the underestimation of the true NPV.
- The ability of the model to predict the presence and particularly the absence of a CBD stone.
- A prospective validation of the model.

- Giving answers about the identification of the optional method of cholangiography (ERCP pre-LC *vs* IOC) by focusing on percentages of undetected stones, morbidity and mortality. This is very important in the minimally invasive surgery era.
- A prediction equation that gives answer to the question of presence or absence of CBD stone for an individual patient.

The policy of selective preoperative ERC before laparoscopic cholecystectomy has been proposed in some reports^[13,14]. Stain *et al*, performed preoperative ERCP in all patients with an elevation of more than twice as normal in one of LFT measurements. Approximately, 57.6% of those had stones^[15]. In this study, only laboratory data were assessed and ultrasonographic criteria were not included in the establishment of the predictive model.

Barkun *et al*, determined optimal cut-off values using ROC curve analysis upon retrospective data. Independent predictors were age (cut-off 55 years), bilirubin (over 30 $\mu\text{mol/L}$), presence of a dilated CBD on ultrasonography >6 mm and suspected or detected bile duct stone (at ultrasonography). The model was validated prospectively. A CBD stone was predicted with a probability ranging from 19% to 38%, when none or only one criterion was present to 49-94%, when three or four criteria were fulfilled^[16].

In the current series of patients enrolled according to the selection criteria, a total of 60 out of 78 patients (28 of 36 patients in group A and 32 of 42 patients in group B accounting for 76.9%), were found to have CBD stones, which in our opinion is a well acceptable result.

We conclude that selection criteria such as equal or greater than twice normal values of dBil, ALP, SGOT and CBD diameter ≥ 10 mm on ultrasound can be objectively applied to predict the presence of CBD stones.

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