Research Article

Development of a scoring system with laboratory and ultrasound parameters to predict the choledocholithiasis

Abstract

Importance: ERCP is an effective method for this pathology but requires that reliable preoperative markers for the presence of choledocholithiasis are established to reduce the number of unnecessary endoscopic procedures.

Objective: Develop a system of scoring with ultrasound and laboratory parameters to predict choledocholithiasis.

Design, setting, and participants: It is an analytical, prospective, and quantitative study tested diagnostic (sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratio). The universe is represented by a total of 600 patients that were treated in the surgery service of the Hospital with Hepatobiliopancreatic pathology, the sample is represented by 400 patients of the universe, from January 2012 to July 2016.

Exposures: It was conducted using a pre-established protocol review of medical records of Viedma Clinical Hospital.

Main Outcome and Measures Determine if using simple a lab test along with the abdominal ultrasound, you can predict the existence of choledocholithiasis and decide to perform therapeutic ERCP.

Results: By subjecting all patients studied to the scoring scale, we can see that those with one higher score (add of) >4 have a 31% chance to find stones in the bile duct, and which those which have a score <4 have a 5% chance to find stones in his bile duct, therefore the use of this scoring scale allows us to predict 6 times the probability of present gallstones in the bile duct that if we don't use the same.

Conclusion and relevance: The use of diagnostic tests (sensitivity, specificity, predictive value, and likelihood ratio) are effective tests for their discriminatory power between sick and healthy patients. Patients with 4 or more criteria achieve a sensitivity of 66% and a specificity of 90% to predict choledocholithiasis.

Dr. Gonzalo Torres Ortiz C,[1] Jorge Luis Navarro A,[2] Dra. Isabel Torres Ortiz V[3]
[1]Cirujano General Servicio Cirugía Hospital Viedma, Profesor Cirugía Universidad Mayor San Simón, Bolivia
[2]Residente IV de Cirugía General, Hospital Clínico Viedma, Bolivia
[3]Médica Cirujana, Universidad Mayor de San Simón, Bolivia

Correspondence: Gonzalo Torres Ortiz C, Cirujano General Servicio Cirugía Hospital Viedma, Profesor Cirugía Universidad Mayor San Simón, Cochabamba, Bolivia, Email sotoguzmanjazminshan@gmail.com

Received: April 16, 2023 | **Published:** May 08, 2023

Introduction

Cholelithiasis is a very common disease that involves approximately 15% of the population of Europe and North America. In 5-20% of cases it is complicated by choledocholithiasis, which is defined as the presence of stones in the common bile duct, and is located in the 8% to 18% of patients with symptomatic cholelithiasis and at least 3% to 10% of the patients that are brought to cholecystectomy. Currently, there is a consensus that the stones in the common bile duct must be removed, regardless of the patient's symptoms, since his tenure can produce not only pain but pancreatitis and/or cholangitis. Clinically biliary obstruction may have the following stages:

a) Patients whom is ERCP considered surgical treatment by having clinical symptoms and findings suggestive ultrasound of biliary obstruction.

b) Patients with acute symptoms that give spontaneously and then have abdominal pain, jaundice, and fever regardless of simultaneous alterations in the liver profile.

c) Patients with biliary emergencies (acute cholangitis) or pancreatic (acute pancreatitis).

Depending on the circumstances, management will be individualized by the specialist with options such as endoscopic sphincterotomy with Endoscopic Retrograde Cholangiopancreatography (ERCP), intraoperative cholangiography (CIO), and the choledocotomy (CLDT), both open and laparoscopic. Howevere, the available therapeutic options, diagnosing choledocholithiasis in many circumstances is not easy. Clinical evaluation and serum biochemical tests often are not enough to make an accurate diagnosis of choledocholithiasis, being necessary to perform confirmatory imaging which can be invasive and non-invasive. The first (includes" ERCP and CIO, and between the seconds (secondes hepatobiliary ultrasound, magnetic resonance cholangiography, and the echo endoscopy.

Justification

While there is a wide range of diagnostic tests and therapeutic procedures for choledocholithiasis management, ERCP is located in a privileged place, showing 80 to100% effective in the removal of litos in the bile duct, similar to those reported for open exploration of the bile duct. ERCP has a mortality rate of 0.15 to 2.2% and morbidity of 0 to 17%, so, while it is an effective method for this pathology, requires that they establish reliable preoperative markers for the presence of choledocholithiasis to decrease the number of unnecessary endoscopic procedures, since it is well defined that the use of ERCP, before elective open surgery, is not a cost-effient procedure and which increases morbidity. Because of the inherent risks of ERCP, this is considered a test primarily therapeutic, indicated

when other not invasive tests identified biliopancreatic pathology. However, there are other more sensitive and specific tests to determine the existence of choledocholithiasis as cholangiography by magnetic resonance imaging and the biliopancreatic endosonography, but they are expensive tests and not available in all institutions. Therefore we decided to study patients undergoing ERCP, to identify the exact parameters to predict effectively those patients with increased risk for choledocholithiasis, according to their clinical, biochemical and ultrasound characteristics. And to determine if using simple lab tests, along with the abdominal ultrasound, you can predict the existence of choledocholithiasis and decide to perform therapeutic ERCP.

Methodological Design

It is an analytical, prospective, and quantitative study tested diagnostic (sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratio). It was conducted using a preestablished protocol review of medical records of Viedma Clinical Hospital clinical from January 2012 to July 2016. The universe is represented by a total of 600 patients that were treated in the surgery service of the Hospital with Hepatobiliopancreatic pathology, the sample is represented by 400 patients of the universe. Between inclusion criteria, we had: Patients with hepatobiliopancreatic pathology, ultrasound of gallbladder and biliary tract, values of bilirubin, gamma glutamyl transferase (GGT) and alkaline phosphatase (ALP) y ERCP. Exclusion criteria like: Patients who do not meet 1 or more inclusion criteria, patients with malignant disease of the gallbladder and biliary tract, and patients with other comorbidities.

Results

However, 50% of patients with common bile duct stones had high alkaline phosphatase to a comparison of the ones that were without gallstones are 1.25% only. Also appreciates that GGT is high at 2.5% of patients who have stones in the common bile duct and is practically not high in the ones that do not have stones in the common bile duct (Figure 1). In the 40% of patients with common bile duct stones present dilatation of the duct and 43.75% of patients do not present expansion despite the presence of stones in the common bile duct (Figure 2). The 62.5% of patients who have stones in the common bile duct presented high total bilirubin (TBIL) and direct bilirubin (BC) and only 6% of patients with common bile duct stones presented high total bilirubin and indirect bilirubin (BU) (Table 1).

The 69.5% of patients that held the ERCP had no choledocholithiasis and only 30.5% of patients who held the ERCP presented choledocholithiasis (Figure 3).

A score greater than or equal to 4 allows us to predict the presence of choledocholithiasis. The 31.25% of patients who presented choledocholithiasis had a score >4 and the 47.5% of patients who did not have choledocholithiasis had a score < 4 (Figura 4).
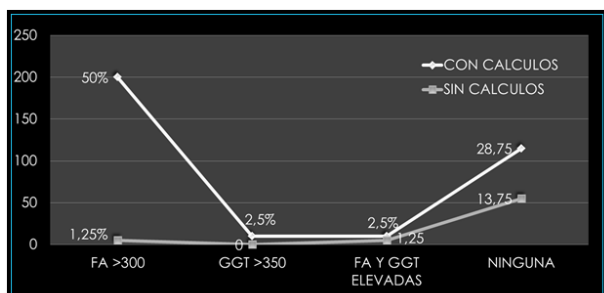

Figure 1 Patients with and without gallstones in the common bile duct that apply for alkaline phosphatase (ALP) and gamma glutamyl transferase (GGT).
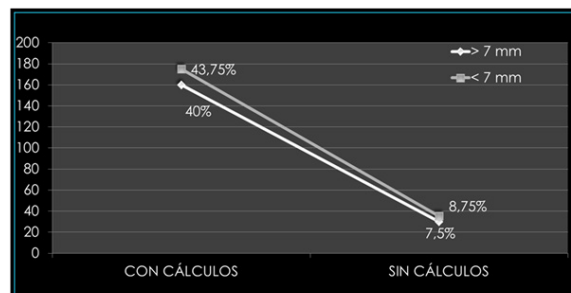

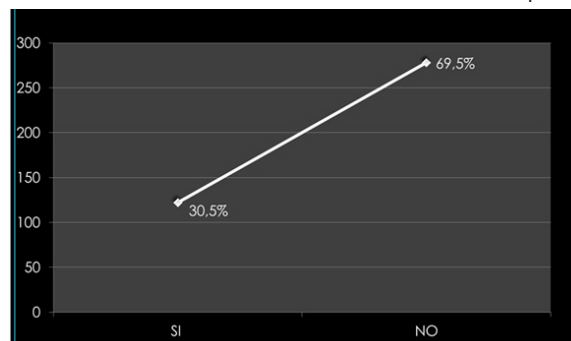**Figure 2** Patients with and without common bile duct dilatation post-ERCP.

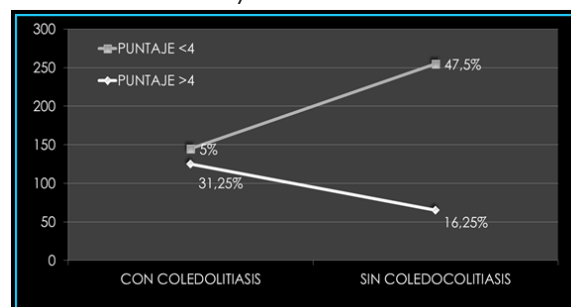**Figure 3** Choledocholithiasis by ERCP.

Figure 4 Patients with and without choledocholithiasis whom held the score.

Table 1 Patients with and without gallstones who requested TBIL and BC

	Con Cálculos	Sin Cálculos
BT >1.2 y BD >0,6	250(62.5%)	40(10%)
BT >1,2 y BI >1	24(6%)	18(4.5%)
Ninguna	48(12%)	20(5%)

Table 2 Alkaline Phosphatase

S - Sensibilidad	0.63	IC 95%	0.93 - 0.98
E - Especificidad	0.85	IC 95%	0.93 - 0.98
LR+ - Razón de Probabilidad positiva	4.07	IC 95%	1.24 - 1.52
LR-- Razón de Probabilidad negativa	0.44	IC 95%	1.24 - 1.52
VPP - Valor Predictivo Positivo	0.95	IC 95%	0.93 - 0.98
VPN-Valor Predictivo Negativo	0.31	IC 95%	0.93 - 0.98

Sensitivity: 63% Specificity: 85% VPP: 95%

Table 3 Gamma Glutamyl Transferase

S - Sensibilidad	0.06	IC 95%	0.64 - 0.96
E - Especificidad	0.92	IC 95%	0.64 - 0.96
LR+ - Razón de Probabilidad positiva	0.78	IC 95%	0.78 - 1.16
LR-- Razón de Probabilidad negativa	1.02	IC 95%	0.78 - 1.16
VPP - Valor Predictivo Positivo	0.8	IC 95%	0.64 - 0.96
VPN-Valor Predictivo Negativo	0.16	IC 95%	0.64 - 0.96

Sensitivity: 6%   Specificity: 92%   VPP: 80%

Table 4 High Total Bilirubin + Direct Bilirubin

S - Sensibilidad	0.78	IC 95%	0.82 - 0.9
E - Especificidad	0.49	IC 95%	0.82 - 0.9
LR+ - Razón de Probabilidad positiva	1.51	IC 95%	1.14 - 1.52
LR-- Razón de Probabilidad negativa	0.46	IC 95%	1.14 - 1.52
VPP - Valor Predictivo Positivo	0.86	IC 95%	0.82 - 0.9
VPN-Valor Predictivo Negativo	0.35	IC 95%	0.82 - 0.9

Sensibility: 78%   Specificity: 49%   VPP: 86%

Table 5 High Total Bilirubin + Indirect Bilirubin

S - Sensibilidad	0.07	IC 95%	0.42 - 0.72
E - Especificidad	0.77	IC 95%	0.42 - 0.72
LR+ - Razón de Probabilidad positiva	0.32	IC 95%	0.53 – 0.9
LR-- Razón de Probabilidad negativa	1.2	IC 95%	0.53 – 0.9
VPP - Valor Predictivo Positivo	0.57	IC 95%	0.42 - 0.72
VPN-Valor Predictivo Negativo	0.17	IC 95%	0.42 - 0.72

Sensibility: 7%   Specificity: 77%   VPP: 57%

Table 6 Common Bile Duct Dilatation

S - Sensibilidad	0.48	IC 95%	0.79 - 0.89
E - Especificidad	0.54	IC 95%	0.79 - 0.89
LR+ - Razón de Probabilidad positiva	1.03	IC 95%	0.93 – 1.1
LR-- Razón de Probabilidad negativa	0.97	IC 95%	0.93 – 1.1
VPP - Valor Predictivo Positivo	0.84	IC 95%	0.79 - 0.89
VPN-Valor Predictivo Negativo	0.17	IC 95%	0.79 - 0.89

Sensibility: 48%   Specificity: 54%   VPP: 84%

Table 7 Scoring Scale

	SCORE
BT : >1,2 mg/dl	1
BD: >0,6 mg/dl	1
FA: >300 mg/dl	2
GGT: >350 mg/dl	2
Common bile duct ultrasound : >7mm	1

Table 8 Relationship of Predictors of Choledocholithiasis and ERCP

S - Sensibilidad	0.66	IC 95%	0.81 - 0.92
E - Especificidad	0.9	IC 95%	0.81 - 0.92
LR+ - Razón de Probabilidad positiva	6.91	IC 95%	2.71 – 4.21
LR-- Razón de Probabilidad negativa	0.38	IC 95%	2.71 – 4.21
VPP - Valor Predictivo Positivo	0.86	IC 95%	0.81 - 0.92
VPN-Valor Predictivo Negativo	0.75	IC 95%	0.81 - 0.92

Sensibility: 66%   Specificity: 90%

Discussion and conclusion

The use of diagnostic tests (sensitivity, specificity, predictive value, and likelihood ratio) are effective tests for their discriminatory power between sick and healthy patients. In our study, the laboratory and ultrasound parameters had a marked high sensitivity and positive predictive value, with rates similar to other scientific work. Alkaline phosphatase is an enzyme marker of, intrahepatic cholestasis and its elevation (2.5 - 3 times greater than its normal value) has a sensitivity of 85% for choledocholithiasis. In our work, the sensitivity was 63%, specificity 85%, and 90% of positive predictive value for which was given a score of 2.

GGT is another sensitive enzyme and is predictive of cholestasis. Our research had a sensitivity of 6%, but we consider that this sensitivity is due to our cutoff value being >350 which is 6 times higher than its normal value, but by multiple scientific papers, we believe that this is more specific of hepatobiliary disease and therefore its use is common and it is considered a marker more sensitive of choledocholithiasis. Therefore despite its sensitivity in our work, it is assigned also a score of 2, by background before.

The work yielded a sensitivity of 48% and a specificity of 54% for the ultrasound of the common bile duct dilatation findings, we conclude that these low values occurred because in our service we do not have the appropriate equipment, or the experience to be able to assess the common bile duct diameter. To total, direct bilirubin and common bile duct dilatation with similar sensitivity and specificity, the score was 1 for each of them.

The highest predictive values were obtained in descending order: alkaline phosphatase, direct bilirubin, total bilirubin, ultrasound, and GGT. By subjecting all patients studied to the scoring scale, we can see that one higher score >4 have a 31% chance to find stones in the bile duct, and those who have a score <4 have a 5% chance to find stones in his bile duct, therefore the use of this scoring scale allows us to predict 6 times the probability of present gallstones in the bile duct that if we don't use the same. Therefore we conclude that patients with 4 or more criteria achieve a sensitivity of 66% and a specificity of 90% to predict choledocholithiasis, and if before this study in the Viedma Hospital 69.5% of ERCP were unnecessary, applying this system has the probability that 66% of patients will have a more accurate indication of a therapeutic ERCP.

Conflicts of Interest

None.

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