Normal biliary tract in patients with suspected choledocholithiasis undergoing ERCP: A case-control study

Vía biliar normal en pacientes con sospecha de coledocolitiasis sometidos a CPRE estudio de casos y controles

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ABSTRACT

Introduction: one of the main complications of cholelithiasis is choledocholithiasis. Endoscopic retrograde cholangiopancreatography (ERCP) is the treatment of choice. **Objective:** to differentiate and predict a normal result during endoscopic retrograde cholangiopancreatography. **Material and methods:** a case-control study was performed in patients who underwent endoscopic retrograde cholangiopancreatography for suspected choledocholithiasis in groups of cases with patients with normal biliary tract and patients with choledocholithiasis as controls. Age, cannulation, procedure time, bile duct size, total, direct and indirect bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), amylase before endoscopic retrograde cholangiopancreatography, pancreatitis before the procedure, pancreatitis after endoscopic retrograde cholangiopancreatography, and ASGE (American Society for Gastrointestinal Endoscopy) risk were evaluated. **Results:** statistically significant differences were only found in cannulation attempts, 4.1 vs. 3.0, p = 0.02; bile duct size, 5.2 mm vs. 11.4 mm, p < 0.001; and alanine aminotransferase concentration, 207.1 U/l vs. 291.9 U/l, p = 0.01. **Conclusions:** it was impossible to differentiate between patients with normal biliary tract and those with choledocholithiasis with the variables studied. A proportion of patients with normal biliary tract had spontaneously resolved choledocholithiasis.

RESUMEN

Introducción: una de las principales complicaciones de la colelitiasis es la coledocolitiasis. La colangiopancreatografía retrógrada endoscópica (CPRE) es el tratamiento de elección. Objetivo: diferenciar y predecir un resultado normal durante una colangiopancreatografía retrógrada endoscópica. Material y métodos: se realizó un estudio de casos y controles en pacientes que fueron sometidos a colangiopancreatografía retrógrada endoscópica por sospecha de coledocolitiasis en grupos de casos con pacientes con vía biliar normal y controles con pacientes con coledocolitiasis. Se evaluaron edad, canulación, tiempo de procedimiento, tamaño de la vía biliar, bilirrubina total, directa e indirecta, aspartato aminotransferasa (AST), alanina aminotransferasa (ALT), amilasa previa colangiopancreatografía retrógrada endoscópica, pancreatitis previa a procedimiento, pancreatitis post colangiopancreatografía retrógrada endoscópica, riesgo ASGE (American Society for Gastrointestinal Endoscopy). Resultados: sólo se encontraron diferencias con significancia estadística en intentos de canulación, 4.1 vs 3.0, p = 0.02; tamaño de la vía biliar, 5.2 mm vs 11.4 mm, p < 0.001; y en la concentración de alanina aminotransferasa, 207.1 U/l vs 291.9 U/l, p = 0.01. Conclusiones: no fue posible diferenciar entre los pacientes que cursan con vía biliar normal y pacientes con coledocolitiasis con las variables estudiadas. Es probable que una proporción de pacientes con vía biliar normal hayan cursado con una coledocolitiasis resuelta de manera espontánea.

Abbreviations:
ALT = alanine aminotransferase
AST = aspartate aminotransferase
ERCP = endoscopic retrograde cholangiopancreatography
MCR = magnetic cholangioresonance
EUS = endoscopic ultrasound
HPB-US = abdominal hepatobiliary ultrasound

INTRODUCTION

Cholelithiasis is the presence of lithiasis within the gallbladder; some complications include cholecystitis, hydrops, vesicular empyema, choledocholithiasis, and Mirizzi syndrome, among others.[1] Choledocholithiasis means one or more lithiasis within the common bile duct. It has two origins, the primary one occurs when the stones originate in the bile duct (10% of cases) and the secondary one when the stones migrate from the gallbladder (90% of cases).[2] Obstructive symptoms are the main characteristic of choledocholithiasis and include pain, jaundice, cholangitis, and pancreatitis.[3] However, it can also be asymptomatic in up to 13% of cases.[4] The treatment of this pathology is mainly performed endoscopically using endoscopic retrograde cholangiopancreatography (ERCP);[5] however, it is not the only way to treat this entity; open or laparoscopic exploration of the biliary tract is the second most used technique or a combination of both techniques (endoscopic and laparoscopic) may also be used.[6] For its diagnosis, hepatobiliary abdominal ultrasound (HPB-US) is the first study to be performed on these patients due to its high availability in second-level centers. However, it has a sensitivity of 75% for detecting choledocholithiasis[7] and 66.5% for detecting dilated biliary tract.[8] Studies such as magnetic cholangioresonance (MCR) and endoscopic ultrasound (EUS) have taken place in the diagnosis of choledocholithiasis (with an accuracy of 94.7% and a precision of 95%, respectively),[9,10] although their availability is limited in our environment. ERCP has a sensitivity of up to 93% and a specificity of 100% to detect lithiasis in the common bile duct;[2] however, its diagnostic role has been limited, and its main usefulness at present is therapeutic. The request for ERCP in patients with suspected bile duct obstruction is based on clinical criteria and imaging studies. However, 47.5% (very low) concordance has been found between pre- and post-ERCP diagnosis.[11] More than 20% of ERCPs will report normal results (normal bile duct, without filling defects). These patients will likely have undergone a fully therapeutic procedure with considerable risks. Studies such as MCR and EUS could avoid performing these procedures in this group of patients; however, the lack of availability in most second-level centers means that the percentage of ERCP with normal results does not decrease. Although the clinical criteria for suspected choledocholithiasis are accessible and easy to use, their sensitivity and specificity may be low. This study aims to evaluate which characteristics could differentiate and predict a normal result during ERCP.

MATERIAL AND METHODS

A retrospective case-control study was performed, including female patients who underwent ERCP for suspected choledocholithiasis (patients with gallbladder *in situ* and ultrasonographic diagnosis of cholelithiasis) during the period from January to December 2019 at the Hospital General de Zona No. 35, Instituto Mexicano del Seguro Social. Group 1, or "cases", consisted of records whose results were described as normal, while group 2, or "controls", consisted of records whose results were described as choledocholithiasis proven during ERCP. Patients with incomplete information were excluded as well as those who met the criteria (post-ERCP) for complex choledocholithiasis and/or cholangitis.

All patients had to undergo ERCP, which was considered adequate when the procedure was able to perform cannulation (with a 0.035″ hydrophilic guide) in the bile duct through the major papilla and a cholangiography after fully identifying the extrahepatic bile duct, the hepatic confluence, and the intrahepatic bile ducts. A cholangiography with a bile duct without

dilatation (6 mm) and/or filling defect in any portions was considered a standard bile duct. Choledocholithiasis was considered when there was evidence of filling defects considered as lithos and evidence of its extraction. The following variables were evaluated: age, the number of cannulation attempts, procedure time, common bile duct size (measured with cholangiography during ERCP), total, direct and indirect bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), pre-ERCP amylase, difficult cannulation, pre-procedure pancreatitis, post-ERCP pancreatitis, and ASGE risk *(Table 1)*.[12] Difficult cannulation was considered based on the criteria established by the European Society for Gastrointestinal Endoscopy (ESGE): 5-5-2 (more than five minutes in cannulation time, five or more cannulation attempts, two or more unintentional cannulations to the pancreas).[13] As this was a case-control study, the information was collected retrospectively, so submitting the protocol to the hospital bioethics committee for approval was unnecessary.

The results of the variables were presented as average, standard deviation, and proportions using the statistical program SPSS® version 29 (IBM©). The Student's t-test was used to compare averages, the Levene test for equality of variances was used for variables with normal behavior, and the Mann-Whitney U test for variables with abnormal behavior; the Kolmogórov-Smirnov test was used to determine the goodness of distribution fit of distributions. The χ^2 test was used for two or more groups to compare proportions. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 87 patients were included, 39 patients in group 1 and 48 patients in group 2. *Table 2* shows the comparison of the variables studied in both groups. A statistically significant difference was found in the number of cannulation attempts (higher in group 1), the size of the bile duct (higher in group 2), and the ALT value obtained (higher in group 2); the rest of the variables did not show a statistically significant difference.

Table 3 shows the percentage of patients at risk according to the ASGE criteria without finding statistically significant differences for medium and high risk. *Figure 1* shows the total number of patients classified by ASGE risk in each group. A similar proportion is observed between the groups in their comparison, which does not show a significant statistical difference.

DISCUSSION

When comparing the mean age of the groups, there was no significant statistical difference. These mean ages coincide with other studies, in which the age ranged between 42 years.[14] Classically, a cut-off point for age, around 40 years, has been established as a risk factor for cholelithiasis, and therefore, the risk of suffering choledocholithiasis is 5-20%.[15,16] This mean age coincides with the appearance of pathologies due to metabolic alterations such as hypertension, dyslipidemia, obesity, type 2 diabetes, and hepatic disease due to steatosis. Thus, cholelithiasis has been proposed as the biliary representation of the metabolic syndrome.[17,18]

Table 1: Criteria for choledocholithiasis according to ASGE.	
Predictors	**Definition**
Very strong	Choledocholithiasis on ultrasound
	Cholangitis clinic (*Tokyo* 18)
	Bilirubin > 4 mg/dl
Strong	Common bile duct > 6 mm by ultrasound (with gallbladder *in situ*)
	Bilirubin 1.8 to 4 mg/dl
Moderate	Alteration of liver biochemistry
	Age > 55 years old
	Diagnosis of acute biliary pancreatitis
High-risk	Presence of one very strong predictor or two strong predictors
Medium risk	Presence of a strong and/or moderate predictor
Low risk	No presence of any predictor

ASGE = American Society for Gastrointestinal Endoscopy.

Table 2: Variables studied by group.			
Variable	**Group 1 (N = 39)**	**Group 2 (N = 48)**	**p**
Age (years)	47.9 ± 14.9	45 ± 16.4	0.700*
Cannulation attempts	4.1 ± 2.5	3.0 ± 2.0	0.020‡
ERCP time (minutes)	38.7 ± 6.1	38.8 ± 6.7	0.100*
Bile duct size (mm)	5.2 ± 1.2	11.4 ± 5.4	> 0.001‡
Total bilirubin (mg/dl)	3.1 ± 2.1	4.0 ± 2.5	0.200*
Direct bilirubin (mg/dl)	1.8 ± 1.3	2.4 ± 1.7	0.090*
Indirect bilirubin (mg/dl)	1.3 ± 0.9	1.6 ± 0.9	0.300‡
ALT (U/l)	207.1 ± 194.4	291.9 ± 248.1	0.010‡
AST (U/l)	181.6 ± 224.0	214 ± 190.2	0.500‡
Pre-ERCP amylase (U/l)	285.7 ± 572.1	169.7 ± 312.0	0.400‡
Difficult cannulation (n, %)	19 (48.7%)	17 (35.4%)	0.200§
Pancreatitis on admission (n, %)	6 (15.4%)	6 (12.5%)	0.700§
Post-ERCP pancreatitis (n, %)	4 (10.3%)	7 (14.6%)	0.800§

* Student's t test.
‡ Mann-Whitney U test.
§ χ^2 or Fisher's exact test if applicable.
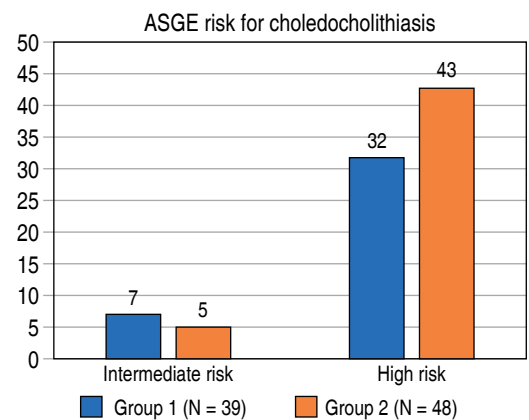Source: electronic file HGZ No. 35-IMSS.

Table 3: ASGE risk by group.			
	Intermediate risk **N = 12** **n (%)**	**High risk** **N = 75** **n (%)**	**p**
Group 1 (N = 39)	7 (18.0)	32 (82.0)	0.36*
Group 2 (N = 48)	5 (10.4)	43 (89.6)	

* χ^2 or Fisher's exact test if applicable.
Source: electronic file HGZ No. 35-IMSS.

Figure 1: Total number of patients stratified by risk and their comparison according to groups.
Source: electronic file HGZ No. 35-IMSS.

attempts was 4.1 (group 1) vs 3.0 (group 2) with a difference of 1.1 attempts (p-value = 0.02). When this variable was categorized as difficult cannulation, there was no statistically significant difference (48.7 vs. 35.4%, p = 0.2); however, the difference between these proportions is greater than 10% (13.3%), giving clinical significance.[19] Cannulation of a normal bile duct is considered a difficult maneuver, which carries a higher risk of post-ERCP complications.

There was no difference in procedure time between the groups (38.7 min vs. 38.8 min, p = 0.1), with a shorter time than that observed in other centers (average of 66.5 min during ERCP).[20] However, we must consider that most centers with publications on ERCP have staff in training and that this average time includes all diagnoses, so we must consider that our endoscopic time (normal biliary tract or simple choledocholithiasis) will not be similar to a procedure with complex choledocholithiasis or malignant tumor.

Bile duct size was another variable with a statistically significant difference (5.2 mm vs 11.4 mm, p ≥ 0.001); this data was obtained from cholangiography during ERCP. It is important to mention that up to 41.3% of patients with proven choledocholithiasis will have a normal caliber of the bile duct,[21] so a caliber < 6 mm does not rule out the presence of bile duct stones, at least in

Cannulation attempts were higher in group 1; a standard bile duct is related to a difficult cannulation and, therefore, a higher number of cannulation attempts. In this study, the number of cannulation

four out of 10 patients. These lithos will have a spontaneous clearance in up to 71% of cases.[22] Therefore, it is possible that patients in group 1 could have had choledocholithiasis resolved spontaneously before the ERCP, leaving no trace of bile duct dilatation or evidence of papillary "blooming". It has been observed that during routine cholecystectomy (without suspicion of choledocholithiasis), 3.4% of these patients will have an occult or asymptomatic choledocholithiasis, which will resolve spontaneously in 30% of patients within up to six weeks after cholecystectomy.[23] Such resolution should be suspected when the patient presents with pain identical to biliary colic during convalescence. Group 1 showed an elevation of total bilirubin by 3.1 mg/dl (direct 1.8 mg/dl, indirect 1.3 mg/dl) with no significant statistical difference (p = 0.2) in group 2 (total bilirubin 4.0 mg/dl, direct 2.4 mg/dl, indirect 1.6 mg/dl). Elevated bilirubin values are adequate to suspect choledocholithiasis (according to ASGE). However, Mariscal and colleagues found hyperbilirubinemia in 46.3% of patients with acute cholecystitis, proving choledocholithiasis in only 7.3% of patients. These authors observed that patients tend to have decreased bilirubin values 48 to 72 hours after admission. They recommend performing laparoscopic cholecystectomy and transoperative cholangiography safely and without delay on these patients.[24] These patients likely have difficulty in bile flow originating from vesicular inflammation affecting the bile duct without causing dilatation of the bile duct and/or transient choledocholithiasis. The mean ALT was another marker with a significant statistical difference (207.1 U/l vs. 291.4 U/l, p = 0.01). This enzyme is predominantly (but not exclusively) located in the hepatic cytoplasm.[25] Similar ALT values have been observed in patients with cholecystitis vs. choledocholithiasis (118 U/l vs. 280 U/l, p = 0.000).[26] Liver enzyme values are likely to be elevated during cholecystitis, suggesting (according to ASGE) a moderate criterion for choledocholithiasis. It has been proposed that ALT values greater than 400 U/l may

suggest choledocholithiasis (although the degree of elevation has no relation to the severity of choledocholithiasis). This elevation of ALT is related to the evolution of choledocholithiasis, so the longer the time of cholestasis, the higher ALT levels, and the reduction to normal (or almost normal) levels occurs after permeabilization of the biliary tract.[27]

The mean amylase levels (285.7 U/l vs. 169.7 U/l, p = 0.4) and the proportion of patients with pancreatitis on admission (15.4 vs. 12.5%, p = 0.7) showed no significant statistical difference between groups. These results support the hypothesis of transient calculus in group 1. The incidence of post-ERCP pancreatitis had no significant statistical difference between the two groups (10.3 vs. 14.6%, p = 0.8); its incidence was slightly higher than that reported in the literature, ranging from 3.4 to 9.7%.[28]

Gaudi et al. observed 88 typical cases (12%) in 734 procedures in their study, of which 46% of patients had a low risk, 40% of patients had a medium risk, and only 14% of patients had a high risk of choledocholithiasis.[29] In our study, in the standard group, 18% had medium risk, and 82% had high risk. It is likely that these inverse proportions, between Gaudi's study and ours were explained because our patients had a gallbladder *in situ*, which makes it possible that some of the patients with normal cholangiography may have had spontaneously resolved choledocholithiasis (as mentioned above), which suggests reassigning the risk of the patients on admission when scheduling and performing ERCP.

The role of ERCP as a treatment for choledocholithiasis is clear; this procedure avoids exploration of the biliary tract in up to 93% of cases and significantly reduces hospitalization days.[30] Currently, the use of ERCP for the diagnosis of choledocholithiasis remains a dilemma due to the risk of adverse events (5 to 13%)[31] including pancreatitis (7%), bleeding (2%), infection or cholangitis (1%), and perforation (0.6%), and a mortality rate less than 1%.[32-36] However, the lack of access to sensitive and specific studies to detect choledocholithiasis such as MCR

and EUS, and the diagnostic limitation of HPB-US place a dilemma when it comes to using or not using a morbid tool such as ERCP in patients with medium or low risk when requested by the attending physicians. Currently, the ASGE criteria are the most accessible tool for determining the risk of choledocholithiasis and, therefore, the need for ERCP. Although their use seems to reduce the incidence of cholangitis and other complications,[37] contradictory results have been found regarding the sensitivity and specificity of these criteria in Mexican centers and other countries.[38-40] This study has weaknesses, such as being performed in a single center. The number of variables should be expanded. However, it is likely to be a snapshot of what happens in most of the second-level public centers in the country.

ERCP is a complex procedure, and although the most common request is for choledocholithiasis, the variety of post-ERCP diagnoses is wide,[41,42] These include an expected result in up to 21% of cases.[40,43] Normal ERCP results appear to be inherent to the procedure. These are likely to spontaneously resolve choledocholithiasis, as up to 71% of patients with simple choledocholithiasis (less than 5 mm), clear or resolve without adjuvant treatment. Other patients may have criteria for choledocholithiasis (ASGE) when gallbladder inflammation reaches or affects the biliary tract or even the perihepatic area, thus affecting the criteria and placing the patient at intermediate or high risk of choledocholithiasis. On the other hand, 15% of patients with normal ERCP had biliary pancreatitis, which supports the hypothesis of a transient litho.

CONCLUSIONS

In our study, it was not possible to determine what percentage of patients with normal ERCP results had transient or spontaneously resolved choledocholithiasis. More clinical tools are required to predict or differentiate patients with normal biliary tract (with medium and high risk by ASGE) from those with choledocholithiasis.

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