Trend in predictive factors of choledocholithiasis: the key to the management of pediatric patients with suspected gallstones

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Abstract

Objectives. To reduce the overuse of magnetic resonance cholangiopancreatography and the rates of non-therapeutic endoscopic retrograde cholangiopancreatography in pediatric patients suspected of choledocholithiasis.

Materials and methods. Retrospective study of patients suspected of choledocholithiasis between January 2010 and June 2023. Patients with cholangitis or two or more of the following predictive factors of choledocholithiasis in initial laboratory tests and ultrasound were categorized as high-risk group: total bilirubin level ≥ 2 mg/dl, common bile duct > 6 millimeters on ultrasound; and detection of choledocholithiasis by ultrasound. Patients were recategorized according to the results of the second set of laboratory and ultrasound analysis. Confirmatory modalities (magnetic resonance cholangiopancreatography, endoscopic retrograde cholangiopancreatography, and/or intraoperative cholangiography) were used to evaluate the presence of choledocholithiasis. Finally, we assessed the predictive capability of both the initial high-risk group and the group after recategorization.

Results. A total of 129 patients were included. After initial studies, 72 (55.8%) patients were classified into the high-risk group. After recategorization, only 29 (22.5%) patients were included in this group. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of the initial high-risk group were 89.3%, 53.5%, 34.7%, 94.7%, and 61.2%, respectively, while after recategorization, they were 82.1%, 94.1%, 79.3%, 95.0%, and 91.5%, respectively.

Conclusions. Recategorization of the risk of choledocholithiasis would significantly improve the diagnostic accuracy of choledocholithiasis and help reduce the overuse of more complex and unnecessary studies/procedures.

Key Words: Choledocholithiasis; Magnetic resonance cholangiopancreatography; Endoscopic retrograde cholangiopancreatography; Spontaneous remission; Algorithm.

Tendencia en los factores predictivos de coledocolitiasis: la clave para el manejo de pacientes pediátricos con sospecha de cálculos en la vía biliar

Resumen

Objetivos. Disminuir la sobre indicación de la colangiorresonancia y las tasas de colangiopancreatografía retrógrada endoscópica o terapéuticas en pacientes pediátricos con sospecha de coledocolitiasis.

Material y métodos. Estudio retrospectivo de pacientes con sospecha de coledocolitiasis entre enero de 2010 y junio de 2023. Los pacientes con colangitis o dos o más de los siguientes factores predictivos de coledocolitiasis en las pruebas de laboratorio y ecografía iniciales, se categorizaron como grupo de alto riesgo: nivel de bilirrubina total ≥ 2 mg/dl, colédoco > 6 milímetros en ecografía; y la detección de coledocolitiasis por ecografía. Los pacientes fueron recategorizados de acuerdo a los resultados del segundo conjunto de análisis de laboratorio y ecografía. Para evaluar la presencia de coledocolitiasis se utilizaron modalidades confirmatorias (colangiorresonancia, colangiopancreatografía retrógrada endoscópica y/o colangiografía intraoperatoria). Finalmente, evaluamos la capacidad predictiva tanto del grupo de alto riesgo inicial como del grupo después de la recategorización.

Resultados, Se incluyeron 129 pacientes. Luego de los estudios iniciales, 72 (55,8%) pacientes se clasificaron en el grupo de alto riesgo. Luego de la recategorización, solo 29 (22,5%) pacientes fueron incluidos dentro de este grupo. La sensibilidad, especificidad, valor predictivo positivo, valor predictivo negativo y precisión diagnóstica del grupo de alto riesgo inicial fueron de 89,3%, 53,5%, 34,7%, 94,7% y 61,2%, mientras que luego de la recategorización fueron de 82,1%, 94,1%, 79,3%, 95,0% y 91,5%, respectivamente.

Conclusiones. La recategorización del riesgo de coledocolitiasis, mejoraría significativamente la precisión diagnóstica de coledocolitiasis y ayudaría a disminuir la sobre indicación de estudios/procedimientos complejos e innecesarios.

Palabras Clave: Coledocolitiasis; Colangiorresonancia; Colangiopancreatografía retrógrada endoscópica; Resolución espontánea; Algoritmo.

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INTRODUCTION

The prevalence of gallstones in children has risen in recent years, possibly attributed to the growing incidence of childhood obesity[1,2]. The simultaneous presence of stones in the common bile duct is significantly more prevalent among pediatric patients (30%) compared to adults (10%)[3]. Several diagnostic and therapeutic approaches are commonly used for the management of patients with suspected choledocholithiasis (CD), including magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP). To avoid over indication of MRCP and the rates of non-therapeutic ERCP, precise and reproducible risk stratification strategies are necessary.

With this objective, different adult societies developed algorithms and risk scores for the management of patients with suspected CD, based on initial ultrasound (US) and laboratory findings[4-6]. Some of these studies reported that incorporating a second set of laboratory tests did not improve accuracy, and a significant decline in liver function tests did not reliably predict spontaneous stone passage[7-9]. Over the past few years, some pediatric studies have identified specific risk factors and developed risk scores for CD in this population[10-12]. However, the impact of the evolution of laboratory values is not well addressed in pediatric patients, and in the only pediatric study where it was analyzed, the findings correlate with those in adult patients[12].

Based on the high incidence of preoperative spontaneous passage of common bile duct stones in pediatric patients and clinical experience, we hypothesized that inclusion of US and laboratory trends would significantly improve accuracy of current guidelines. The objective of this study was to evaluate how the incorporation of a second set of laboratory tests and abdominal US influenced the diagnostic capacity for pediatric CD.

METHODS

We conducted a retrospective research of all patients with gallstones and suspected CD who underwent cholecystectomy between January 2010 and June 2023. The collected patient information was from J.P. Garrahan Hospital (Buenos Aires, Argentina), a > 500-bed pediatric tertiary referral hospital. During the study period, the most frequent management in these patients consisted of liver function tests and abdominal US on admission. For the initial management of these patients, we include: Fluid resuscitation with normal saline and 5% dextrose to maintain adequate fluid status and urine output. For analgesic treatment, we use dipyrone and hyoscine as an antispasmodic. For refractory pain, we administer intravenous morphine. We do not use prophylactic antibiotics unless there is a diagnosis of cholecystitis or cholangitis. We recommend nothing by mouth and early oral/enteral nutrition within 48-72 hours of presentation. In some cases, second set of laboratory tests and US were drawn 48-96 hours after admission, either intentionally or because of a delay in subsequent evaluation. Then, magnetic resonance cholangiopancreatography (MRCP) or laparoscopic cholecystectomy with intraoperative cholangiography (IOC) was performed, depending on the case and availability. Pre-surgical endoscopic retrograde cholangiopancreatography (ERCP) was performed in cases diagnosed with CD by MRCP. When CD was observed on IOC, common bile duct exploration or postoperative ERCP were performed according to the surgeon's experience.

We included in the analysis only patients with suspected CD who underwent at least 2 sets of liver test and abdominal US. Patients with hemolytic disease, Mirizzi syndrome, pancreaticobiliary maljunction, those without available laboratory and/or US results, and those with only one set of laboratory tests and US were excluded from the study. We defined suspected CD as the presence of any of the following variables: gallstone pancreatitis; ascending cholangitis; elevated total bilirubin, dilated common bile duct on US and the presence of common bile duct stones on US. We defined acute pancreatitis as the presence of at least 2 of the following 3 criteria: abdominal pain compatible with acute pancreatitis; serum amylase and/or lipase activity at least 3 times greater than the upper limit of normal; imaging findings compatible with acute pancreatitis[13]. We defined ascending cholangitis according to the definition proposed by the Tokyo guidelines[14].

The main outcome was the presence of CD on confirmatory modalities (MRCP, ERCP or IOC). If there was a discrepancy between the MRCP and ERCP/IOC findings, the results of the ERCP or IOC were considered the final diagnosis for CD. The presence of "insignificant" or "minimal" biliary sludge in the absence of stones was not considered CD. Patients without confirmatory modalities, who also remained free of subsequent events, were included in the analysis and classified as not having CD. Spontaneous resolution was defining by the following criteria: (1) no evidence of common bile duct stone by confirmatory modalities; (2) positive MRCP followed by ERCP/CIO without radiographic evidence of a persistent stone; and (3) suspected CD without confirmatory modalities, accompanied by the resolution of symptoms, normalization of US findings and laboratory values and with no subsequent events.

We classified patients into two groups: the high-risk (HR) group and the non-high-risk (NO-HR) group for CD based on the HR criteria from our previously published score[10]. This classification was determined using initial laboratory values and abdominal US and was repeated at the time of their subsequent evaluation before MRCP, ERCP, or IOC. Specifically, patients were assigned to the HR group if two or more predictive factors were present, or if ascending cholangitis was diagnosed. The variables

Table 1. General features of the patients according to the presence or absence of choledocholithiasis in confirmatory modalities.

Variables	*Data (n= 129) n (%) o median (IQR)*	*Presence of CDL (n=28) n (%) o median (IQR)*	*Absence of CDL (n=101) n (%) o median (IQR)*	*P-value*
Age at surgery (years)	13 (12-14)	13 (12-14)	13 (12-14)	
Gender				
Female	96 (74.4)	21 (75.0)	75 (74.3)	0.936
Male	33 (25.6)	7 (25.0)	26 (25.7)	
Overweight/Obesity	56 (43.4)	8 (28.6)	48 (47.5)	0.073
Gallstone pancreatitis	72 (55.8)	5 (17.9)	67 (66.3)	< 0.001
Cholangitis	4 (3.1)	4 (14.3)	0 (0.0)	< 0.001
RF for CDL (1st set of studies)	107 (82.9)	28 (100)	79 (78.2)	0.007
TB ≥ 2 mg/dl	72 (55.8)	19 (67.9)	53 (52.5)	0.147
CBD > 6 mm on US	88 (68.2)	27 (96.4)	61 (60.4)	< 0.001
CDL on US	43 (33.3)	18 (64.3)	25 (24.8)	< 0.001
RF for CDL (2nd set of studies)	62 (48.1)	27 (96.4)	35 (34.7)	< 0.001
TB ≥ 2 mg/dl	22 (17.1)	16 (57.1)	6 (5.9)	< 0.001
CBD > 6 mm on US	56 (43.4)	27 (96.4)	29 (28.7)	< 0.001
CDL on US	22 (17.1)	15 (53.6)	7 (6.9)	< 0.001
Confirmatory modalities	92 (71.3)	28 (100)	64 (63.4)	< 0.001
MRCP	80 (62.0)	23 (82.1)	57 (56.4)	0.013
Preoperative ERCP	24 (18.6)	21 (75.0)	3 (2.9)	< 0.001
IOC	55 (42.6)	11 (39.3)	44 (43.6)	0.685

IQR: interquartile range; RF: risk factors; CDL: choledocholithiasis; TB: total bilirubin; CBD: common bile duct; US: ultrasound; MRCP: magnetic resonance cholangiopancreatography; ERCP: endoscopic retrograde cholangiopancreatography; IOC: intraoperative cholangiography.

we defined as predictive factors for CD included a total bilirubin level ≥ 2 mg/dL, a common bile duct measurement of > 6 mm on ultrasound, and the detection of CD on US imaging. We then assessed the predictive capability of the HR criteria both at the initial presentation and after the second set of studies.

Continuous variables are presented as median (interquartile range) and categorical variables as absolute values and percentages. Pearson's/Fisher's chi-square analysis was used to assess associations between categorical variables. P value of < 0.05 was considered as statistically significant. Accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the high-risk criteria were calculated with a 95% CI. Statistical Package for Social Sciences (IBM SPSS, Armonk, NY) version 22.0 was used.

RESULTS

Between January 2010 and June 2023, a total of 267 patients with suspected CD underwent cholecystectomy at our center. Nine patients were excluded due to a diagnosis of hemolytic anemia, 2 for Mirizzi syndrome, 3 for pancreaticobiliary maljunction, 14 lacked available laboratory and/or US results, and an additional 110 were excluded for having only one set of laboratory tests and US. As a result, 129 patients with suspected CD were included in the final analysis. Of these patients, 96 (74,4%) were females. The median age was 13 (12-14) years. Forty three percent of patients were overweight or obese. Out of the 129 patients, 92 (71.3%) underwent one or more confirmatory modalities, revealing CD in 28 (21.7%) cases. Only 4 (3.1%) patients experienced cholangitis, all of whom concurrently exhibited more than 2 predictors of CD. Spontaneous resolution was observed in 103 (79.8%) patients. All cholecystectomies were completed laparoscopically. Median follow-up was 4 (1-18) months. General features of the cohort are summarized in Table 1.

After the initial evaluation, 72/129 (55.8%) patients were classified into the HR group. Out of these, only 25 (34.7%) had diagnosis of CD on the confirmatory studies, and 47 (65.3%) experienced spontaneous resolution. Fifty-seven out of the 129 (44.2%) were classified into

Table 2. Predictive capacity of the high-risk group after the initial and second set of studies.

High risk group	*N (%)*	*Accuracy % (95% CI)*	*Sensitivity % (95% CI)*	*Specificity % (95% CI)*	*PPV % (95% CI)*	*NPV % (95% CI)*	*p-value*
Initial	72 (55.8)	61.2 (52.2-69.6)	89.3 (70.6-97.2)	53.5 (43.3-63.4)	34.7 (24.1-46.9)	94.7 (84.5-98.6)	< 0.0001
Recategorization	29 (22.5)	91.5 (84.9-95.5)	82.1 (62.4-93.2)	94.1 (87.0-97.6)	79.3 (59.7-91.3)	95.0 (88.2-98.1)	< 0.0001

PPV: positive predictive value; NPV: negative predictive value; CI: confidence interval .

the NO-HR group. Among these, 3 (5.3%) had CD, and 56 (98.2%) experienced spontaneous resolution. Based on the initial analysis, the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of the HR criteria for CD were 89.3%, 53.5%, 34.7%, 94.7%, and 61.2%, respectively. In addition, out of the 72 patients in the HR group, 44 (61.1%) were reclassified into the NO-HR group after the second set of studies. In this subgroup, the sensitivity was 88%, and the NPV was 93.2%.

The time between the first and second analysis was 3 (2-4) days. After the second set of studies, 29/129 (22.5%) patients met HR criteria for CD. Out of these, 23 (79.3%) had CD in the confirmatory studies, and only 6 (20.7%) experienced spontaneous resolution. One-hundred (77.5%) were classified into the NO-HR group. Among these, 5 (5.0%) had CD, and 97 (97.0%) evolved with spontaneous resolution. Based on the second set of analysis, the sensitivity, specificity, PPV, NPV, and accuracy of the HR criteria for CD were 82.1%, 94.1%, 79.3%, 95.0%, and 91.5%, respectively (Table 2). If we consider that 2 patients with CD from the NO-HR group experienced spontaneous resolution, the predictive accuracy of the score according to the second set of studies would be even better: 88.5%; 94.2%; 79.3%; 97.0%; 93.0%, respectively.

DISCUSSION

For the management of patients presenting with suspected common bile duct stones, a range of diagnostic approaches, including MRCP and ERCP, is commonly utilized. Nevertheless, it is crucial to acknowledge that these procedures are not devoid of associated complications. Magnetic resonance cholangiopancreatography is not therapeutic and has been associated with extended length of stay, increased utilization of healthcare resources, and the potential requirement for anesthesia, particularly in younger children[12]. Conversely, ERCP, while highly effective in relieving biliary obstruction, carries a risk of 7-15% for post-ERCP pancreatitis and a 1-3% risk of bleeding, as well as risks of perforation, infection, and anesthesia-related adverse events[7,15]. To mitigate these potential complications, there is a need for pediatric-specific scores and algorithms in the management of suspected common bile duct stone.

While CD requires ongoing assessments to enhance both diagnosis and subsequent treatment, current international guidelines for adult patients do not provide recommendations on the necessity of repeating studies before making decisions[4-6]. The majority of adult studies that analyzed the impact of risk factor trends on the predictive capacity of these guidelines concluded that laboratory trends did not enhance diagnostic accuracy, and therefore should not influence clinicians in choosing to forgo definitive testing, such as MRCP[7-9]. Nevertheless, others emphasize the importance of laboratory monitoring and risk reclassification in the precision of CD prediction[16,17].

In pediatrics, there are no international guidelines available, although recently, three groups have published age-specific CD risk scores for the pediatric population[10-12]. However, the diagnostic utility of liver test trends, commonly used in clinical practice to assess the presence of CD, is not well-defined in pediatric patients. The only pediatric study that analyzed the impact of predictive factor trends did not find significant differences in the predictive capacity of its score[12]. In this context, our analysis is the first pediatric study to emphasize the significance of reclassifying the risk for CD after admission.

For the risk categorization of CD, both ASGE and ESGE guidelines employ not only laboratory variables but also US findings. Therefore, it is peculiar that none of the studies that examined the predictive factor trends of CD have analyzed the outcomes of subsequent US and solely relied on laboratory results[7-9,12,16,17]. Our study is the first to dynamically analyze predictive factors for CD in patients with gallstones and suspected CD, taking into consideration not only laboratory studies but also US findings. It is worth noting that, to date, none of the risk scores for choledocholithiasis published include liver enzymes as risk factors, except for bilirubin[5,6,10-12]. This is the reason why we opted against incorporating other liver enzymes in our present study.

Spontaneous migration of CD is frequently observed in pediatric patients[18]. In our study, 80% of all patients suspected of having CD experienced spontaneous resolution. Furthermore, among the patients initially classified as HR for CD, 47/72 (65.3%) exhibited spontaneous resolution,

and 44/72 (61.1%) were subsequently reclassified into the NO-HR group after the second set of evaluations. This conversion rate is notably higher in our pediatric population than what has been reported in adult patients (22.8-35.2%)[7,8]. One potential explanation for this discrepancy may lie in the time interval between the initial and subsequent assessments, which is not consistently reported in various studies[8,12], or is often as short as 6 hours[7]. In contrast, our study maintained an interval of 3 (2-4) days between the initial categorization and subsequent evaluation. In addition, some authors suggest that because most common bile duct stones in pediatric patients will pass spontaneously, with few patients presenting with symptoms of a passing or retained stone, there is a lower urgency for intervention, unless signs of cholangitis occur[18,19]. Considering these factors and the notable rate of spontaneous resolution, especially in patients initially classified as HR, along with the relatively low incidence of ascending cholangitis in pediatric cases, it is crucial to allow an adequate waiting period (48-96 hours) for spontaneous resolution. This period should precede any consideration of additional diagnostic interventions. Repeating laboratory and ultrasound assessments within 48 hours could result in an excessive recommendation for MRCP. This poses the potential risk of elevated rates of non-therapeutic ERCP in cases with false-positive outcomes or clinically insignificant small stones that may resolve spontaneously.

To curtail the excessive use of MRCP and ERCP in patients suspected of common bile duct stone and ensure the most favorable risk-benefit ratio, accurate and reproducible risk stratification methods are imperative. In a prior publication, we demonstrated a notably low incidence of CD (2.7%) in pediatric patients with mild gallstone pancreatitis and lacking associated risk factors for CD[20]. Consequently, in such cases, we recommended laparoscopic cholecystectomy without IOC or other definitive tests for CD. In our current study, building upon our previously published simple scoring system, we observed a significantly enhanced accuracy after patient reclassification as compared to the initial assessment: 61.2 vs 91.5%, respectively. This improvement can be primarily attributed to the significant enhancement in specificity and PPV after reclassification: 53.5 vs 94.1% and 34.7 vs 79.3%, respectively. These findings lend support to the notion that the dynamic evaluation of patients with suspected CD substantially diminishes false positive results, thereby reducing the unnecessary utilization of complex studies such as MRCP and the incidence of non-therapeutic ERCP procedures.

The primary limitations of our study include its retrospective nature and the relatively small sample size, as it is a single-center investigation. Nevertheless, this study represents a foundational contribution to pediatric evidence regarding the efficacy of repeating laboratory tests and abdominal ultrasound in patients with suspected common bile duct stone. Another limitation is the inclusion of patients without confirmatory studies. However, since the publication of our risk score in 2021[10], we have refrained from requesting confirmatory studies for patients without predictive factors after the second set of analyses. Additionally, every patient without confirmatory modalities had shown improvement in all risk predictors in the second set of analyses and remained free of subsequent events. In these cases, it is evident that spontaneous stone migration occurred. Lastly, our study did not assess length of stay or associated costs. While this diagnostic strategy may potentially extend the length of stay and related costs, it is likely to significantly reduce the overutilization of MRCP and ERCP, thereby mitigating costs and complications associated with these procedures. Future investigations could address these limitations through larger-scale, randomized prospective data collection, as well as multi-institutional studies.

In conclusion, the dynamic evaluation of patients with suspected common bile duct stones, along with the recategorization of CD risk based on repeat laboratory studies and abdominal ultrasound, enhances the predictive capacity of the score. Consequently, this approach is expected to decrease the rate of unnecessary procedures.

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