

Dynamic changes in liver function tests do not correctly reclassify patients at risk of choledocholithiasis beyond ASGE 2019 criteria

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Abstract

Introduction: Dynamic changes in liver function tests have been proposed to correctly reclassify the risk of choledocholithiasis; however, information is scarce and insufficient to recommend its use.

Methods: Retrospective cohort of patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) due to moderate and high risk of choledocholithiasis according to the 2019 American Society of Gastrointestinal Endoscopy (ASGE) guidelines. We evaluated whether significant changes in liver function tests (bilirubin, transaminases, or alkaline phosphatase), defined as an increase or a reduction ≥ 30 or $\geq 50\%$ between two measurements taken with a difference of 24–72 h can correctly reclassify the risk of choledocholithiasis beyond the ASGE guidelines. The net reclassification index (NRI) was calculated for patients with and without choledocholithiasis.

Results: Among 1175 patients who underwent ERCP, 170 patients were included in the analysis (59.4% women, median 59.5 years). Among patients without a diagnosis of choledocholithiasis, the number of patients correctly reclassified by transaminases was slightly higher than those incorrectly reclassified (NRI=0.24 for aspartate amino transaminase and 0.20 for alanine amino transaminase). However, among patients with a diagnosis of choledocholithiasis, it led to incorrect reclassification in a greater number of cases (NRI = -0.21 and -0.14, respectively). The benefits of reclassification were minimal for bilirubin and alkaline phosphatase, or for value changes $>50\%$. A subgroup analysis showed similar findings in patients without a history of cholecystectomy and in those with normal bile duct.

Conclusion: Dynamic changes in liver function tests do not improve choledocholithiasis risk classification beyond the 2019 ASGE criteria. New criteria should continue to be sought to optimize risk stratification.

Keywords: American Society for Gastrointestinal Endoscopy, choledocholithiasis, common bile duct stone, endoscopic retrograde cholangiopancreatography, clinical enzyme tests

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Introduction

Choledocholithiasis is responsible for more than 1.4 million annual emergency department visits,^{1,2} with indirect costs of approximately \$6.5 billion annually in the United States.^{3,4} Stone removal by endoscopic retrograde cholangiopancreatography (ERCP) is the preferred treatment, but is a complex endoscopic procedure associated

with life-threatening complications, such as post-ERCP pancreatitis, hemorrhage, perforation, and infection,^{5,6} so it is reserved for cases where clinical suspicion is very high. In patients with a low clinical suspicion, it is preferable to make the diagnosis with less invasive evaluations such as magnetic resonance cholangiopancreatography (MRCP) or endoscopic ultrasound (EUS).⁷

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Scientific societies recommend stratifying the probability of having choledocholithiasis through identifiable predictors in clinical presentation, biochemical tests, and abdominal ultrasound findings,⁸ restricting ERCP only to patients with the highest risk. The most frequently used stratification algorithm was developed by the American Society of Gastrointestinal Endoscopy (ASGE).⁹ In 2010, a first version was proposed that classified patients into low risk (<10% probability), intermediate risk (10–50%), and high risk (>50%). As a high-risk criterion, the presence of any of the following predictors was established: (1) ascending cholangitis, (2) choledocholithiasis visualized in imagen, (3) total bilirubin >4 mg/dL, or (4) the simultaneous appearance of a dilated common bile duct on ultrasound (>6 mm in a patient with gallbladder or >8 mm in cholecystectomy) and bilirubin level between 1.8 and 4 mg/dL. Intermediate risk was classified as those with the presence of one strong predictor (common bile duct dilatation or moderate elevation of bilirubin) or any moderate predictor (abnormal liver biochemical tests other than bilirubin, age over 55 years and clinical biliary pancreatitis), and as low risk those without any of these predictors present.

After the publication of the first ASGE guidelines, several evaluations concluded that these criteria had a suboptimal performance, and their application would lead to unnecessary ERCP in more than one-third of patients, resulting in an unacceptable risk of potential complications.^{10–12} Therefore, ASGE modified its stratification tool in 2019 seeking to improve diagnostic accuracy in the high-risk group. The new high-risk criteria include: (1) ascending cholangitis, (2) choledocholithiasis in ultrasound or abdominal CT, or (3) total bilirubin >4 mg/dL plus dilated common bile duct. With intermediate risk: (1) abnormal liver biochemical other than bilirubin, (2) age over 55 years, and (3) common bile duct in the image are included. The recommendations derived from this stratification were not modified: ERCP to patients at high risk, and MRCP or EUS to patients at intermediate risk. Recent evaluations comparing the previous 2010 criteria with those of 2019 have consistently found an improvement in specificity without reaching the desired optimal level,^{13–15} so new methods have been proposed to improve the identification of patients who can be taken directly to ERCP, trying to minimize the proportion of negative studies.¹⁶

One of the complementary methods to assess the likelihood of choledocholithiasis is the evaluation of dynamic changes in liver function tests,^{17–19} considering that stones can migrate in the biliary tree and modify these parameters. However, to date, the information is scarce and insufficient to recommend or limit its use, especially considering the methodological limitations of previous studies, such as the variable and often excessive time between paraclinical measurements and confirmation of choledocholithiasis, and the lack of a single gold standard for diagnosis, which has led to divergent results.

The aim of this study is to evaluate whether dynamic changes in liver function tests (defined as an increase or decrease greater than 30% or 50% in two measurements), with a minimum difference of 24 h and a maximum difference of 72 h, can correctly reclassify patients at intermediate or high risk of choledocholithiasis, using the ASGE 2019 criteria as a baseline and considering ERCP as the only gold standard. To this end, we evaluate the net reclassification index (NRI),²⁰ a measure increasingly used to evaluate improvements in risk prediction by estimating the incorporation of new parameters into validated statistical models.

Methods

A retrospective cohort study was designed which included all hospitalized patients who underwent ERCP for moderate and high risk choledocholithiasis according to ASGE 2019 guidelines at the Hospital Universitario San Ignacio (HUSI) in Bogotá, Colombia between 1 January 2015 and 31 December 2022. Patients with a history of choledocholithiasis, previous biliary intervention, known liver disease, and gastric or biliary surgery (Roux-en-Y gastric bypass, Billroth I or II, cholecystojejunostomy, or hepaticojejunostomy) were excluded, as were patients with acute conditions such as sepsis and septic shock, and those who did not have two liver function test measurements with a minimum of 24 h and a maximum of 72 h between them before undergoing ERCP. In addition, patients with failed ERCP (where cannulation of the duodenal papilla was not achieved) and those who underwent ERCP six or more days after admission were excluded. The study was approved by the Ethics Committee of the Hospital Universitario San Ignacio and the Pontificia Universidad Javeriana.

Patients were identified from a database that systematically records all ERCPs performed by the HUSI Gastroenterology Service. After reviewing the inclusion and exclusion criteria, information was collected from the institutional electronic medical records, including demographic variables, paraclinical reports [bilirubin, transaminases, and alkaline phosphatase (ALP) levels], available imaging studies (abdominal ultrasound, scenography, nuclear magnetic resonance, MRCP, or EUS), and the written report of ERCP, using a standardized format.

Patients at high and intermediate risk for choledocholithiasis were defined according to previously established ASGE 2019 criteria. A diagnosis of choledocholithiasis on ERCP was considered if stones, stone fragments, or biliary sludge were seen in the duodenal lumen. Significant changes in liver function tests for the diagnosis of choledocholithiasis were considered as an increase $\geq 30\%$ or $\geq 50\%$ between the two measurements, with a minimum difference of 24 h and a maximum difference of 72 h. A decrease $\geq 30\%$ or $\geq 50\%$ of the same tests was considered a criterion for excluding the diagnosis. If there were more than two measurements in this period, the second most different value was chosen.

Continuous variables with a normal distribution are presented as mean and standard deviation and those without as median and interquartile range. The Shapiro–Wilk test was used to assess the assumption of normality. Categorical variables are presented as absolute frequencies and percentages.

To assess the extent to which the risk of choledocholithiasis is correctly or incorrectly reclassified, the category-based NRI²¹ was used, evaluating the addition of the marker of significant change in liver function tests to the 2019 ASGE criteria. The entire sample was first stratified into intermediate- and high-risk categories, separating for analysis the groups with confirmed and excluded diagnosis of choledocholithiasis by ERCP. Within each group, the percentage of patients correctly or incorrectly reclassified with the addition of the new variable was evaluated. Changes in risk classification were quantified by the NRI, with each of its components reported independently: event NRI (confirmed diagnosis of choledocholithiasis) and non-event NRI (exclusion of choledocholithiasis). Statistical analysis was performed using the

STATA 16[®] statistical package (StataCorp, College Station, TX, USA).

Results

We identified 1175 unique patients who underwent ERCP on their first admission. We excluded 233 patients whose primary indication was not suspected choledocholithiasis (201 for malignant stenosis, 32 for bile duct revision for suspected postoperative injury), 56 for history of choledocholithiasis with previous bile duct intervention, 10 for known liver disease, 17 for septic shock or sepsis, 3 for Roux-en-Y gastric bypass, 1 for Billroth II, and 63 for ERCP performed six or more days after admission. A total of 602 patients did not have two liver function tests available within the specified time.

Finally, 170 patients were included in the analysis. The general characteristics of the patients are shown in Table 1. Of the total number of patients, 59.4% were women ($n = 101$), the mean age was 59.5 years (IQR: 32–72), and 22.9% had a history of cholecystectomy. Patients without choledocholithiasis had higher ALP levels (median 378 *versus* 251 U/L, $p = 0.023$) and were more likely to have total bilirubin levels > 4 mg/dL (40.4% *versus* 67.6%, $p = 0.004$). On the other hand, patients with choledocholithiasis had higher AST levels (246 *versus* 203 U/L, $p = 0.019$). Abdominal ultrasound documented common bile duct stones in 30 patients (17.6%), of whom 27 were diagnosed with choledocholithiasis. Common bile duct diameter was larger in patients without choledocholithiasis (9.75 *versus* 7.9 mm, $p = 0.002$). A total of 70.6% of patients were classified as high risk according to ASGE 2019 criteria. Six patients had complications related to ERCP, four cases of bleeding, and two cases of post-ERCP pancreatitis.

Table 2 shows the NRI corresponding to a 30% change in liver function tests. Among patients without a diagnosis of choledocholithiasis, the number of correctly reclassified patients was slightly higher than the number of incorrectly reclassified patients (NRI = 0.24 for AST and 0.20 for ALT). However, among patients diagnosed with choledocholithiasis, incorrect reclassification occurred in a greater number of cases (NRI = -0.21 and -0.14 , respectively). The benefit of reclassification was minimal for bilirubin and ALP.

Table 1. General characteristics of the population according to the diagnosis of choledocholithiasis.

Variable	Total	Choledocholithiasis	No choledocholithiasis	p Value
	(n = 170)	(n = 136)	(n = 34)	
Age, years, median (IQR)	59.5 (32–72)	55 (38.5–72.5)	67.5 (43–72)	0.374
Sex, female, n (%)	101 (59.4)	81 (59.5)	20 (58.8)	0.938
Cholecystectomy, n (%)	39 (22.9)	32 (23.5)	7 (20.6)	0.715
Common bile duct diameter (mm), median (IQR)	8 (6–11)	7.9 (6–10.3)	9.75 (8–14)	0.002*
<6 mm	38 (22.3)	33 (24.2)	5 (14.7)	
6–8 mm	38 (22.3)	36 (26.5)	2 (5.8)	0.005*
>8 mm	94 (55.3)	67 (49.3)	27 (79.4)	
Cholecystitis, n (%)	50 (29.4)	39 (28.7)	11 (32.4)	0.674
Finding of neoplasm*	9 (5.4)	0 (0)	9 (26.5)	<0.001*
Laboratories at entry				
BT > 4 mg mg/dL, n (%)	78 (45.9)	55 (40.4)	23 (67.6)	0.004*
ALP, median (IQR)	281 (159–420)	251 (150–398)	378 (216–546)	0.023*
AST, median (IQR)	232.5 (139–454)	246 (144.5–554.5)	203 (132–324)	0.019*
ALT, median (IQR)	314.5 (182–533)	320 (181–550.5)	283 (191–406)	0.19
Risk according to ASGE 2019				
High	82 (48.2)	58 (42.6)	24 (70.6)	0.004
Intermediate	88 (51.8)	78 (57.3)	10 (29.4)	
Common bile duct calculations by USE or CT imaging, n (%)	30 (17.6)	27 (19.5)	3 (8.82)	0.131
Cholangitis on admission, n (%)	20 (11.8)	15 (11.0)	5 (14.7)	0.552
BT > 4 mg/dL plus biliary dilatation, n (%)	78 (45.9)	55 (40.4)	23 (67.5)	0.004*
Abnormal liver biochemistry other than bilirubin, n (%)	168 (98.8)	135 (99.3)	33 (97.0)	0.221
Age > 55 years, n (%)	89 (52.4)	66 (48.5)	23 (67.5)	0.046
Bile duct dilation, n (%)	89 (52.4)	66 (48.5)	23 (67.5)	0.046

ALP, alkaline phosphatase; ALT, alanine aminotransferase; AST, aspartate aminotransferase; BT, total bilirubin; CT, computed axial tomography; IQR, interquartile range.

*Considered significant if $p < 0.05$.

Table 3 shows the NRI for 50% changes in liver function tests. In patients without choledocholithiasis, AST correctly reclassified more patients than it incorrectly reclassified (NRI = 0.18), but in patients with choledocholithiasis, the situation was reversed (NRI = -0.16). The benefit of

reclassification was minimal for ALT, bilirubin, and ALP.

Finally, a subgroup analysis was performed in the population without a history of cholecystectomy, and in those with a normal bile duct (common

Table 2. Net reclassification rate – 30% changes.

	No choledocholithiasis <i>n</i> = 34		Choledocholithiasis <i>n</i> = 136		Total
AST					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	8	2	69	9	88
High	10	14	38	20	82
Total	18	16	107	29	170
NRI no event: $10 - 2/34 = 0.24$; NRI with event: $9 - 38/136 = -0.21$					
ALT					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	8	2	67	11	88
High	9	15	30	28	82
Total	17	17	97	39	170
NRI no event: $9 - 2/34 = 0.20$; NRI with event: $11 - 30/136 = -0.14$					
Total bilirubin					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	7	3	52	26	88
High	6	18	25	33	82
Total	13	21	77	59	170
NRI no event: $6 - 3/34 = 0.09$; NRI with event: $26 - 25/136 = 0.007$					
Alkaline phosphatase*					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	5	4	69	7	88
High	5	19	11	43	82
Total	10	23	80	50	163
NRI without event: $5 - 4/33 = 0.03$; NRI with event: $7 - 11/130 = -0.03$					
<p>Among patients without choledocholithiasis, patients correctly reclassified (moving from high-risk to intermediate-risk) are shown in light green and incorrectly reclassified patients (moving from intermediate-risk to high-risk) are shown in orange. Patients no reclassified are in gray. For the calculation of the NRI without event, the incorrectly classified patients are subtracted from the correct ones and divided by the total number ($n = 34$). Among patients with choledocholithiasis, patients correctly reclassified (moving from intermediate risk to high-risk) are shown in light green and incorrectly reclassified patients (moving from high-risk to intermediate) are shown in orange. For the calculation of the NRI with event, the incorrectly classified ones are subtracted from the correct ones and divided by the total number ($n = 136$). *It was calculated on 163 patients with second available measurement. ALT, alanine aminotransferase; AST, aspartate aminotransferase; ASGE, American Society of Gastrointestinal Endoscopy; NRI, net reclassification index.</p>					

bile duct <8 mm), with values close to 0 for the NRI in both patients with and without choledocholithiasis, similar to what was found in the general population (Table 4).

Discussion

Our data suggest that the addition of dynamic changes in liver function tests (defined as 30% or 50% changes in measurements between 24 and

Table 3. Net reclassification rate – 50% changes.

	No choledocholithiasis <i>n</i> = 34		Choledocholithiasis <i>n</i> = 136		Total
AST					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	8	2	70	8	88
High	8	16	30	28	82
Total	16	18	100	36	170
NRI no event: $8 - 2/34 = 0.18$; NRI with event: $8 - 30/136 = -0.16$					
ALT					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	9	1	73	5	88
High	3	21	11	47	82
Total	12	22	84	52	170
NRI no event: $3 - 1/34 = 0.06$; NRI with event: $5 - 11/136 = -0.04$					
Total bilirubin					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	7	3	57	21	88
High	4	20	15	43	82
Total	11	23	72	64	170
NRI without event: $4 - 3/34 = 0.06$; NRI with event: $21 - 15/136 = 0.04$					
Alkaline phosphatase*					
ASGE 2019/NRI	Intermediate	High	Intermediate	High	
Intermediate	6	3	72	4	88
High	1	23	1	53	82
Total	7	26	73	57	163
NRI without event: $1 - 3/34 = -0.06$; NRI with event: $4 - 1/136 = 0.02$					
<p>Among patients without choledocholithiasis, patients correctly reclassified (moving from high-risk to intermediate-risk) are shown in light green and incorrectly reclassified patients (moving from intermediate-risk to high-risk) are shown in orange. Patients not reclassified are in gray. For the calculation of the NRI without event, the incorrectly classified patients are subtracted from the correct ones and divided by the total number (<i>n</i> = 34). Among patients with choledocholithiasis, patients correctly reclassified (moving from intermediate-risk to high-risk) are shown in light green and incorrectly reclassified patients (moving from high-risk to intermediate) are shown in orange. For the calculation of the NRI with event, the incorrectly classified ones are subtracted from the correct ones and divided by the total number (<i>n</i> = 136).</p> <p>*It was calculated on 163 patients with second available measurement.</p> <p>ALT, alanine aminotransferase; AST, aspartate aminotransferase; ASGE, American Society of Gastrointestinal Endoscopy; NRI, net reclassification index.</p>					

72h before ERCP) does not improve the classification of choledocholithiasis risk over ASGE

criteria 2019, regardless of cholecystectomy history or bile duct diameter.

Table 4. Net rate of reclassification in patients with normal common bile duct, and no history of cholecystectomy.

Enzyme evaluated	With gallbladder		Common bile duct	
	NRI without event	NRI event	NRI without event	NRI event
AST				
30% change	0.15	-0.24	-0.14	-0.04
50% change	0.11	-0.18	0.14	-0.01
ALT				
30% change	0.41	-0.13	0.14	0
50% change	0.04	-0.06	0	0
Bilirubin				
30% change	0.07	0.02	-0.14	0.17
50% change	0	0.05	-0.14	0.16
Alkaline phosphatase				
30% change	-0.04	-0.03	-0.28	0.01
50% change	-0.08	0.01	-0.28	0.03

ALT, alanine aminotransferase; AST, aspartate aminotransferase; NRI, net reclassification index.

It drew attention in our study that 70% of patients without choledocholithiasis were classified as high risk based on the presence of total bilirubin values >4 mg/dL and dilated bile duct. Similarly, we found higher values of bilirubin, ALP, and larger diameter of common bile duct. A possible explanation is that in this subgroup, 26% of patients had findings of malignancy, which was not known before performing the procedure, which may represent the reality of gastroenterology units in reference hospitals such as ours. The above result suggests that some patients in the high-risk category for choledocholithiasis might benefit from prior diagnostic imaging to rule out biliary obstructive malignant syndrome.

In our study, dynamic changes in liver function tests did not improve the risk classification of choledocholithiasis beyond the criteria proposed by ASGE 2019. Although there is a small benefit in patients without choledocholithiasis, where a >30% reduction in AST or ALT correctly reclassifies a greater number of patients from high to intermediate risk, this benefit is lost because a similar proportion of patients with choledocholithiasis are inappropriately reclassified when

moving from high to intermediate risk. Thus, the net clinical benefit is limited and should not be incorporated into decision-making because, although it would reduce the number of unnecessary ERCs, it would also increase the performance of supplemental imaging in high-risk patients who do not need it. When evaluating changes >30% or 50% in bilirubin and ALP, the NRI did not show a significant change in the categorization of risk, neither in the group of patients with choledocholithiasis, nor in the group of patients without it. In conclusion, the monitoring of dynamic changes of liver function tests to reclassify the risk of choledocholithiasis is not recommended, so new criteria for the optimization of risk stratification should continue to be used.

Our study has multiple strengths. First, we assessed the evidence in a consecutive series of all ERCs performed at the institution limiting the risk of disease spectrum bias. Second, we compared the tests with the same gold standard for the diagnosis of choledocholithiasis (ERCP) unlike what was done in previous studies. Third, we standardized the time between the two liver function test measurements, which allows the

findings to be reproduced, and prevents the findings from being secondary to actual changes in the presence of the disease.

However, there are limitations that we must recognize: The number of patients was relatively small, especially in the subgroup of patients without choledocholithiasis, which limits the precision of the estimates. Further studies, probably multicenter, will be needed to confirm these results. In addition, some authors have suggested that the NRI is not a reliable measure because it ignores the relative severity of different types of errors, knowing that different types of model errors have different harms for patients.²¹ However, we report both correct and incorrect reclassifications in both choledocholithiasis and non-choledocholithiasis patients, making it easier to interpret the results by recognizing the consequences of different types of errors in each group.

Conclusion

Dynamic changes in liver function tests do not improve the risk classification of choledocholithiasis beyond the 2019 ASGE criteria. On the other hand, the ASGE classification is suboptimal for determining the risk of choledocholithiasis in the high-risk category since it tends to incorrectly categorize other causes of obstruction such as malignant obstructive biliary syndrome.

Declarations

Ethics approval and consent to participate

This study was conducted with the approval of the Clinical Research Ethics Committee of Pontificia Universidad Javeriana. There was no need for informed consent.

Consent for publication

Not applicable.

Author contributions

Tatiana Ramírez-Peña: Conceptualization; Formal analysis; Investigation; Writing – original draft.

Rómulo Darío Vargas-Rubio: Conceptualization; Investigation; Supervision; Writing – review & editing.

Carlos Ernesto Lombo: Investigation; Supervision; Writing – review & editing.

Luis Miguel Rodríguez-Hortua: Data curation; Investigation; Writing – review & editing.

Oscar Mauricio Muñoz-Velandia: Conceptualization; Formal analysis; Investigation; Methodology; Supervision; Validation; Writing – review & editing.

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Competing interests


The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Availability of data and materials

All data analyzed during this study are available with authors upon request. Further enquiries can be directed to the corresponding author.

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