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VALIDATION OF THE PREDICTIVE CRITERIA OF HIGH RISK FOR CHOLEDOCHOLITHIASIS OF THE AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY, 2010: EXPERIENCE OF A COLOMBIAN CARIBBEAN CENTER

VALIDACIÓN DE LOS CRITERIOS PREDICTIVOS DE ALTO RIESGO PARA COLEDOCOLITIASIS DE LA SOCIEDAD AMERICANA DE ENDOSCOPIA GASTROINTESTINAL, 2010: EXPERIENCIA DE UN CENTRO DEL CARIBE COLOMBIANO

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ABSTRACT

Introduction: Endoscopic retrograde cholangiopancreatography (ERCP) has become the gold standard for diagnosis and treatment of choledocholithiasis. The American Society for Gastrointestinal Endoscopy (ASGE) in 2010 proposed stratifying patients into 3 risk levels; however, studies have found controversial results about the predictive parameters of these diagnostic criteria. The objective of this study is to determine the performance of the high-risk predictive criteria of the ASGE 2010 in the diagnosis of choledocholithiasis in a Colombian Caribbean population. **Methods:** Retrospective cross-sectional study, which included patients with suspected choledocholithiasis, and who were taken for evaluation by ERCP, meeting the criteria proposed by the ASGE of high probability. The result obtained was compared with the presence of choledocholithiasis on ERCP, from which values and 95% confidence intervals were estimated for sensitivity, specificity, positive and negative predictive value, and positive and negative likelihood ratio. **Results:** A total of 118 patient data were included in this study. The median age of the patients was 46 years (IQR= 31; 17- 89); 78% (n= 92) were female. 65.3% (n= 77) were older than 55 years. The ERCP result was positive in 81.4% (n= 96) of the patients. The presence of an altered liver profile (90%) was found to be the most sensitive test, clinical cholangitis (86%) the most specific, the presence of duct lithiasis by US (85%) was the test with the highest positive predictive value, and the presence of duct lithiasis by US (35%) was the test with the highest negative predictive value. **Conclusions:** The predictive parameters of the ASGE 2010 criteria for the diagnosis of choledocholithiasis show variability with respect to the performance proposed in the guidelines.

Key words: Choledocholithiasis; Lithiasis; Diagnostic Techniques and Procedures; Risk Factors. (source: MeSH NLM).

RESUMEN

Introducción: La colangiopancreatografía retrógrada endoscópica (CPRE) se ha convertido en el estándar de oro para el diagnóstico y tratamiento de la coledocolitiasis. La Sociedad Americana de Endoscopia Gastrointestinal (ASGE) propuso en 2010 estratificar a los pacientes en 3 niveles de riesgo; sin embargo, los estudios han encontrado resultados controvertidos sobre los parámetros predictivos de estos criterios diagnósticos. El objetivo de este estudio consiste en determinar el desempeño de los criterios predictivos de alto riesgo de la ASGE 2010 en el diagnóstico de coledocolitiasis en una población del Caribe colombiano. **Métodos:** Estudio transversal retrospectivo, en el que se incluyeron pacientes con sospecha de coledocolitiasis, y que fueron llevados a evaluación por CPRE, cumpliendo los criterios propuestos por la ASGE de alta probabilidad. El resultado obtenido se comparó con la presencia de coledocolitiasis en la CPRE, a partir de la cual se estimaron los valores y los intervalos de confianza del 95% para la sensibilidad, la especificidad, el valor predictivo positivo y negativo, y la razón de probabilidad positiva y negativa. **Resultados:** En este estudio se incluyeron los datos de 118 pacientes. La edad media de los pacientes era de 46 años (RIQ= 31; 17- 89); el 78% (n= 92) eran mujeres. El 65,3% (n= 77) eran mayores de 55 años. El resultado de la CPRE fue positivo en el 81,4% (n= 96) de los pacientes. La presencia de un perfil hepático alterado (90%) resultó ser la prueba más sensible, la colangitis clínica (86%) la más específica, la presencia de litiasis ductal por US (85%) fue la prueba con mayor valor predictivo positivo, y la presencia de litiasis ductal por US (35%) fue la prueba con mayor valor predictivo negativo. **Conclusión:** Los parámetros predictivos de los criterios de la ASGE 2010 para el diagnóstico de coledocolitiasis muestran variabilidad con respecto al rendimiento propuesto en las guías.

Palabras clave: Coledocolitiasis; Litiasis; Técnicas y Procesos Diagnósticos; Factores de Riesgo (fuente: DeCS BIREME).

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INTRODUCTION

The frequency of gallbladder stones increases with age. An absolute prevalence of 15% is estimated in the general population[1]. Particularly, in adults over 65 years old, it is between 15 and 30% and increases from 38 to 53% in octogenarians[2-4]. The frequency of this condition in Colombia is not unrelated to the reported world literature, some studies even report a higher frequency[5]. This disease has a significant portion of the emergency services consultation, being immensely important detect the early appearance of complications associated with the presence of stones[6]. Choledocholithiasis is one of the complications that generates greater morbidity in patients with cholelithiasis, since the interlocking of the stones in the common bile duct and subsequent obstruction can generate episodes of pancreatitis, cholangitis, Mirizzi syndrome, among other complications[4].

Endoscopic retrograde cholangiopancreatography (ERCP) has become the gold standard for diagnosis and treatment of patients with high suspicion of choledocholithiasis[7]. However, due to its high cost, the need for expertise to be performed, and the risk of complications, it should only be performed in patients in whom there is a high suspicion of this pathology[8]. The American Society for Gastrointestinal Endoscopy (ASGE) in 2010 9 proposed stratifying patients into 3 risk levels, based on the suspicion of choledocholithiasis (Table 1), since it is not feasible to perform ERCP in all patients 9. Some Studies have found controversial results on the predictive safety of these diagnostic criteria, which casts doubt on the benefit of applying the recommendations of this guideline[10-13].

Studies in Colombian population about the size of the common bile duct have reported an average of 4.16 mm for patients with gallbladder and 4.88 mm for cholecystectomized patients[3]. The cut-off point for the size of the diseased common bile duct to be taken into account according to the ASGE guidelines is bigger than 6 mm, that is why it would be higher than observed in the Colombian population. Considering these anatomical, technical, economic and epidemiological aspects, the objective of this study was to validate the performance of the predictive criteria of the ASGE 2010 for diagnosis of choledocholithiasis in a high-level hospital belonging to the Colombian Caribbean region.

METHODS

Retrospective cross-sectional study, which included patients with suspected choledocholithiasis, who were taken for evaluation by means of endoscopic retrograde cholangiopancreatography, complying with the criteria proposed by the ASGE of high probability, during the period from January 2016 to January 2020 at the Hospital Universitario del Caribe (HUC), Cartagena - Colombia. The inclusion criterion was defined as all patients over 18 years old with a high probability of choledocholithiasis, who underwent ERCP and who underwent two series of paraclinical tests in a time no longer than 4 weeks. Exclusion criteria were all patients with incomplete complementary examinations, biliary stent, biliary fistula, biliary stricture or injury, chronic liver disease that alters liver function, failed ERCP, a history of cholecystectomy and a set of diagnostic tests performed in the longest time 4 weeks after ERCP.

For patients who met the inclusion criteria, data were collected on: age, date and ERCP result, gender, pancreatitis diagnosis, first set of paraclinics (alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase [FA], gamma glutamyl transpeptidase [GGT], amylase, lipase, total bilirubin, direct bilirubin, indirect bilirubin, diameter of the common bile duct and presence of dilatation of the common bile duct, presence of cholangitis, presence of choledocholithiasis in previous image, second set of paraclinics, alteration in liver profile in the two sets of paraclinics, and change in risk stratification.

Statistical analysis was performed using the SPSS version 25 statistical package. Nominal and ordinal variables were expressed as percentages, while discrete and continuous variables were expressed as median and interquartile range (IQR) given that they did not have a normal distribution. To evaluate the performance of the criteria, the result obtained was compared with the presence of choledocholithiasis in ERCP, from which the values and 95% confidence intervals (CI9 5%) of sensitivity, specificity, positive predictive value were estimated. (PPV) and negative (NPV), positive and negative likelihood ratio (LR) (LR + and LR-).

This research work does not present conflicts of interest, nor is its performance sponsored by entities or companies that have involvement with the investigated field. Likewise, participation in the study is voluntary, previously justifying informed consent

to all participants. The variables to be measured imply the use of non-invasive instruments, so the risk of damage, incidents or adverse events is unlikely. Therefore, the research respected the Declaration of Helsinki, and was classified as a minimal risk study according to resolution 8430 of 1993 of the Ministerio de Salud de Colombia and was endorsed by the Comité de Ética de la Universidad de Cartagena.

RESULTS

A total of 118 patient data were included in this study. The median age of the patients was 46 years old (IQR 31; 17-89); 78% (n = 92) were women and the remaining 22% (n = 26) were men. 65.3% (n = 77) were older than 55 years. At the time of admission, only 19.5% (n = 23) had a diagnosis of pancreatitis, while the remaining 89.5% (n = 95) were not diagnosed with this complication.

In general terms, a total bilirubin between 1.8 and 4 mg / dL was reported in 31.4% (n = 37); while a total bilirubin greater than 4 mg / dL was present in 38.1% (n = 45). Regarding the diameter of the common bile duct, it had a median of 10 mm (6; 3-96); 76.3% (n = 90) had common bile duct dilation; 9.3% (n = 11) had cholangitis, 90.7% (n = 107) had an altered liver profile, and 83.1% (n = 98) previously had choledocholithiasis. The population basic characteristics are summarized in Table 2. Regarding the type of image in which choledocholithiasis had been evidenced, 53.4% (n = 63) was in cholangioresonance and 46.6% (n = 55) was in ultrasound of the total abdomen. The endoscopic retrograde collagiopancreatography (ERCP) result was positive in 81.4% (n = 96) and negative in 18.6% (n = 22).

When performing the second set of hepatic and pancreatic paraclinics an average of 1 week before surgery, re-staging was performed in 53.4% (n = 63), finding that AST had a median of 17 (90; 13-700); the ALT a median of 24.5 (166; 18-1010); the GGT a median of 159.5 (550; 25-1525); the AF a median of 102 (317; 45-1500); blood amylase a median of 44 (120; 17-6000); serum lipase a median of 36 (174; 23-16000); total bilirubin a median of 0.65 (13; 0.1-51.9); indirect bilirubin a median of 0.1 (4; 0.1-14.6) and direct bilirubin a median of 0.4 (1.25; 0.5-49.7). The presence of choledocholithiasis in the restaged patients was 81% (n = 51). The differences between the first and the second set are found in Table 3.

Evaluating the predictive parameters of the 2010 ASGE criteria in the diagnosis of choledocholithiasis, from the data obtained, it was found that the presence of an altered liver profile (90%), the presence of US duct stones (86%)), and common bile duct dilation of> 6 mm (79%) were the most sensitive tests; cholangitis clinic (86%), bilirubin 1.8 to 4 mg / dl (73%), pancreatitis clinic (68%) and age> 55 years (68%), were the most specific tests; the presence of US duct lithiasis (85%), common bile duct dilation> 6 mm (84%) and a bilirubin of 1.8 to 4 mg / dl (84%) were the tests with the highest positive predictive value; the presence of US duct lithiasis (35%), common bile duct dilation> 6 mm (29%) and a bilirubin of 1.8 to 4 mg / dl (20%) were the tests with the highest negative predictive value; the presence of US duct lithiasis (1.26%), common bile duct dilation> 6 mm (1.23%) and a bilirubin of 1.8 to 4 mg / dl (1.19%), were the tests with the highest positive likelihood; and finally, the biliary pancreatitis clinic (1.22%), the cholangitis clinic (1.07%) and a bilirubin> 4 mg / dl (1.05%), were the tests with the highest negative likelihood. The summary of the predictive parameters of all the tests is found in Table 4.

Table 1. Proposed strategy to assign the risk of choledocholithiasis in patients with symptomatic cholelithiasis - ASGE 2010[7].

Choledocholithiasis' Magnitude of predictors	Predictors
Very strong	Common bile duct lithiasis on transabdominal ultra-sonography
	Ascending cholangitis clinic
	Bilirubin> 4 mg / dl
Strong	Common bile duct dilated on ultrasonography (> 6 mm with gallbladder in situ)
	Bilirubin level between 1.8 - 4 mg / dl
Moderate	Impaired liver function tests other than bilirubin
	Age over 55 years
	Biliary pancreatitis clinic
A probability of choledocholithiasis is assigned based on clinical preachers	
Presence of some very strong predictor	High*
Presence of both strong predictors	High*
No presence of predictors	Low°
Other patients	Intermediate+

* High risk: Indication of preoperative ERCP or intraoperative cholangiography.
+ Intermediate risk: Indication of additional imaging studies.
° Low risk: Indication of cholecystectomy without additional studies.

Table 2. Basic characteristics of the study population (n = 118).

Parameter	Median - RIQ
Age in years	46 (31; 17-89)
Sex, women (%)	92 (78%)
Over 55 years old, n (%)	77 (65.3%)
Diagnosis of pancreatitis, n (%)	23 (19.5%)
AST	254 (254; 6-1272)
ALT	236.5 (297; 9-1480)
GGT	572 (345; 86-2420)
FA	319 (285; 72-1520)
Amylase	74.5 (118; 15-6625)
Lipase	91.5 (138; 15-41700)
BT	18.5 (41; 0.3-49.8)
BI	6 (12; 0.1-32.7)
BD	16 (29; 0.1-46.4)
Bilirubin between 1.8 and 4 mg / dl, n (%)	37 (31.4%)
Bilirubin higher than 4 mg / dl, n (%)	45 (38.1%)
Common bile duct diameter, mm	10 (6; 3-96)
Common bile duct dilation, n (%)	90 (76.3%)
Cholangitis, n (%)	11 (9.3%)
Altered liver profile, n (%)	107 (90.7%)
Previous choledocholithiasis, n (%)	98 (83.1%)

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Table 3. Differences between the hepatic and pancreatic paraclinical sets.

Parameters	Median - RIQ	
	Paraclinical initial set	
AST	254 (254; 6-1272)	AST
ALT	236.5 (297; 9-1480)	ALT
GGT	572 (345; 86-2420)	GGT
FA	319 (285; 72-1520)	FA
Amylase	74.5 (118; 15-6625)	Amylase
Lipase	91.5 (138; 15-41700)	Lipase
Total Bilirubin	18.5 (41; 0.3-49.8)	Total Bilirubin
Indirect bilirubin	6 (12; 0.1-32.7)	Indirect bilirubin
Bilirubin direct	16 (29; 0.1-46.4)	Bilirubin direct

Table 4. Found values of the predictive parameters of the 2010 ASGE criteria in the diagnosis of choledocholithiasis.

Predictors	Sensitivity	Specificity	VPP	VPN	LR+	LR-
			% (Confidence interval 95%)			
			Very strong			
Presence of gallstones in the bile duct due to US	86	32	85	35	1.2	0.4
Cholangitis Clinic	8	86	73	18	0.5	1.0
Bilirubin> 4 mg / dl	38	59	80	18	0.9	1.0
			Fuertes			
Common bile duct dilation > 6 mm	79	36	84	29	1.2	0.5
Bilirubin 1.8 to 4 mg / dl	32	73	84	20	1.1	0.9
			Moderate			
Altered liver profile	90	5	80	9	0.9	2
Biliary pan-creatitis clinic	17	68	70	16	0.5	1.2
Age over 55 years	35	68	83	19	1.0	0.9

Tabla 5. Summary of studies that evaluated predictive parameters of choledocholithiasis based on the ASGE guidelines[11,12,13,14,21,22,23].

Authors	Variable	Parameters used					
		Sensitivity	Specificity	VPP	VPN	LR+	LR-
Narváez-Rivera et al. 2016[21]	Calculation presence in US	0.2	0.9	0.7	0.4	2.6	0.8
	Cholangitis Clinic	0.1	0.9	0.7	0.4	2.3	0.8
	Bilirubin> 4 mg / dl	0.6	0.4	0.5	0.4	1.1	0.8
	Common bile duct dilation > 6 mm	0.8	0.3	0.6	0.5	1.2	0.5
	Bilirubin 1.8 to 4 mg / dl	0.2	0.7	0.5	0.4	0.9	1.0
	Altered liver profile	0.9	0.0	0.5	0.5	1.0	0.7
	Biliary pancreatitis clinic	0.2	0.5	0.3	0.3	0.4	1.4
	Age over 55 years	0.3	0.7	0.6	0.4	1.4	0.8
Suarez et al. 2016[13]	Calculation presence in US	14.1	97.1	76.9	61.9	-	-
	Bilirubin >4 mg/dl	29.6	84.3	56.8	63.2	-	-
	Altered liver profile	17.1	89.7	68.4	45.2	-	-
	Biliary pancreatitis clinic	55.6	76.3	52.6	78.4	-	-

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He et al. 2017[22]	Calculation presence in US	44	97	91	73	15.9	0.5
	Cholangitis Clinic	20	84	44	61	1.2	0.9
	Bilirubin >4 mg/dl	22	94	69	65	3.5	0.8
	Common bile duct dilation > 6 mm	75	63	57	79	2.0	0.4
	Bilirubin 1.8 to 4 mg / dl	44	80	59	69	2.2	0.7
	Altered liver profile	77	50	50	77	1.5	0.4
	Biliary pancreatitis clinic	10	85	29	59	0.6	1.0
	Age over 55 years	60	54	46	67	1.3	0.7
Gómez Hinojosa et al. 201814	Calculation presence in US	50.3	63.4	69.4	43.7	1.3	0.7
	Cholangitis Clinic	36.6	81.7	76.7	43.9	2.0	0.7
	Bilirubin> 4 mg / dl	42.5	40.9	54.2	30.2	0.7	1.4
	Common bile duct dilation > 6 mm	90.2	15.1	63.6	48.3	1.0	0.6
	Bilirubin 1.8 to 4 mg / dl	34.6	76.3	70.7	41.5	1.4	0.8
	Altered liver profile	92.8	8.6	62.6	42.1	1.0	0.7
	Biliary pancreatitis clinic	23.5	49.5	43.4	28.2	0.4	1.5
	Age over 55 years	39.9	79.6	76.2	44.6	2	0.7

Chandran A et al. 2021[12]	Calculation presence in US	21.1	91	86.5	29.8	2.3	0.8
	Cholangitis Clinic	12.3	93.5	83.7	28.2	1.8	0.9
	Bilirubin> 4 mg / dl	26.5	77	75.8	27.8	1.1	0.9
Jagtap et al. 2020[11]	Calculation presence in US	99.6	61.9	98.2	87.9	-	-
	Cholangitis Clinic	98.9	22.8	88.7	78.0	-	-
	Common bile duct dilation > 6 mm	68.5	69.9	44.4	86.3	-	-
	Altered liver profile	38.5	90.2	34.5	91.6	-	-
	Biliary pancreatitis clinic	55.0	23.1	15.6	66.5	-	-
	Age over 55 years	69.4	36.9	30.3	75.3	-	-
Jacob et al. 2021[23]	Calculation presence in US	17	92	-	-	-	-
	Bilirubin >4 mg/dl	66	51	-	-	-	-
	Common bile duct dilation > 6 mm	40	79	-	-	-	-
	Bilirubin 1.8 to 4 mg / dl	48	55	-	-	-	-
	Biliary pancreatitis clinic	20	53	-	-	-	-
	Age over 55 years	17	83	-	-	-	-

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DISCUSSION

Currently, choledocholithiasis represents the most common cause of obstructive jaundice and cholangitis[16], with various diagnostic tools with predictive parameters subject to anatomical and sociodemographic variables, which implies the absence of an optimal and personalized approach to this type of patient. Based on the above, it was proposed to carry out this study to analyze the performance of the predictive criteria of the ASGE 2010 in the diagnosis of choledocholithiasis in a Colombian Caribbean population. In the last two decades, several studies have been carried out evaluating the clinical variables associated with the appearance of choledocholithiasis in patients with cholelithiasis. Menezes et al[17] in 2000, indicated how parameters such as age (> 55 years), female sex, jaundice, cholangitis, AST, ALT, and ultrasound bile duct dilation could predict the presence of choledocholithiasis; hand in hand, Sgourakis et al18 in 2005 stated that total bilirubin, alkaline phosphatase, AST and ultrasound bile duct dilation should be used, which served as the basis for the creation of the ASGE 2010 criteria[7], distributed between the magnitude of your prediction (very strong, strong, moderate). However, later studies were replicated to corroborate the predictive value of these criteria, finding different performance rates[19,20]. The summary of studies that evaluated the predictive parameters of choledocholithiasis based on the ASGE guidelines is found in Table 5[11,12,13,14,21,22,23].

In this study, as reported in the literature, the presence of bile duct stones by US is the strongest predictor associated with the diagnosis of choledocholithiasis[11,12,13,14,21,22,23]. Although some studies describe the usefulness of biliary pancreatitis as a predictor of choledocholithiasis [11,12,13,14,21,22,23], in the present work, no statistically significant association was found with the diagnosis of choledocholithiasis. However, this difference has also been reported[15]; probably due to the difference in the sample size and undescribed pathological history. Common bile duct dilation> 6 mm is a subjective variable, since certain characteristics such as body mass index, the presence of previous cholecystectomy, or age (since it has been found that the diameter of the common bile duct increases 1 mm every 10 years from 60 years, causing a slight dilation in adulthood), influence this predictor[24].

Based on the above, it can be observed how other authors have achieved differences between these predictive values, and have attributed this divergence to the same causes[11,12,13,14,21,22,23]. However, contrasting with studies that also analyzed the differences between the 2010 and 2019 ASGE guidelines, it was found that divergence persists in terms of the performance of the diagnostic criteria. Chandran et al[12] carried out a retrospective study that included 744 American patients with suspected choledocholithiasis, who underwent ERCP[12]. When contrasting the specificity between the two guidelines, a notable improvement was noted (46.5% to 76%; p <0.001), however, there were no statistically significant changes between the positive and negative predictive values[12]. In contrast, Jacob et al[23] carried out a cohort study with 267 patients with suspected choledocholithiasis, observing that the 2010 ASGE criteria for the diagnosis of choledocholithiasis had a higher predictive value (sensitivity: 68% - specificity: 55%) , compared to the 2019 criteria (sensitivity: 37% - specificity: 80%)[23]. Despite the existence of this divergence between the parameters and obtaining a low performance, Jacob et al[23] concluded that the 2019 criteria reduce the use of ERCP for the diagnosis of choledocholithiasis, a statement that should be supported by better quality evidence.

Unlike He et al22 who used a sample of 2724 patients with suspected choledocholithiasis, of which 43% met high-risk criteria (1171 patients)[22]. The authors obtained a cut-off score, determining that the high-risk (very strong) criteria have a probability of diagnosis> 50%[22]. When grouping criteria (presence of abdominal US stone and / or bilirubin levels> 4 mg / dl + dilated common bile duct) they found greater specificity and positive predictive value; factors to take into account in future studies. Likewise, the increase in the sample allowed choosing a precise probabilistic score (> 50%)[22]. However, this study was carried out in a population of Asian origin (China); variable to consider regarding anatomical variations. Therefore, different reasons continue to be found that could explain the variability of the performance of these criteria; However, most of the authors conclude that as these criteria have a performance equal to or greater than 50%, half of the ERCPs performed are unnecessary[11,13,14,21].

Unlike the contrasted studies, a highlight of this study is the evaluation of the 2 laboratory sets 1 month before surgery and a second set approximately 1 week before surgery, where biochemical parameters were evaluated, obtaining

a new re-staging of previously assessed patients. Of these, Adams et al20 represented the difference between the predictions of the laboratory sets, finding little variation between bilirubin> 4 mg / dl (first set: sensitivity 30.1%, specificity 82.5%, positive predictive value 55.8% and negative predictive value 60.3% vs second set: sensitivity 22.3%, specificity 85.6%, positive predictive value 52.9% and negative predictive value 60.3%); in general, among all the biochemical markers, the variation was not significant (first set: sensitivity 47.4%, specificity 73.0%, positive predictive value 56.3% and negative predictive value 65.4% vs second set: sensitivity 46.3%, specificity 75.5% , positive predictive value 57.8% and negative predictive value 65.9%)[20]. Nevertheless, the sample evaluated was small (179 patients) and they were only evaluated in high-risk patients[20]. Similar results were found by Suarez et al[13], who carried out a retrospective study that included 174 patients, observing that the variability between laboratory sets was not significant either (first set: sensitivity 54.9%, specificity 68.6%, positive predictive value 54.9% and negative predictive value 68.6% vs second set: sensitivity 56.9%, specificity 67.1%, positive predictive value 56.9% and negative predictive value 67.1%)[13]. However, in this study, the performance of the second set allowed re-staging in more than 50% of the patients, so this point should be evaluated in greater depth.

This study is part of the few carried out in Latin America and the Caribbean, which sought to evaluate the performance of the ASGE criteria in the diagnosis of choledocholithiasis[14,15,21], which help us to requalify and know the behavior of choledocholithiasis at the regional and national. As limitations, in the first instance, the analyzed population was 118

patients, it would have been preferred to study a larger population to obtain greater statistical power. In the second measure, other variables added by the linearity of the retrospective study were not analyzed. Third, no associations were estimated that would allow determining the risk or protection value of each variable. However, this study was carried out to strengthen the lines of research in general surgery and to corroborate whether the predictive parameters proposed by the ASGE have the same performance in all populations, and it could be determined that, based on what was proposed in this study, it is not like this.

t is necessary to carry out multicenter prospective studies which allow the analysis of a considerable sample, to obtain statistical strength and power, to be able to make correlations and new estimates. Based on the results, it is also imperative to be constantly attentive to the behavior of the criteria vis-à-vis the natural population served and from the Colombian Caribbean, to guarantee safety and effectiveness in the discard, diagnosis and proper management of choledocholithiasis.

CONCLUSIONS

The predictive parameters of the high-risk criteria for choledocholithiasis according to the American Society for Gastrointestinal Endoscopy, 2010, show variability respecting the performance stated in the guideline. There are no significant differences between performing a first set and a second set of laboratories for risk restaging. However, this depends on the general context of the patient and added factors. It is necessary to develop personalized criteria adapted to the factors that influence and alter this performance.

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