Comparison of the Diagnostic Performance of the ASGE 2019 Criteria and the C-IMP for Choledocholithiasis in Patients Undergoing ERCP

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ABSTRACT

Introduction. Choledocholithiasis is a frequent complication of cholelithiasis (10–20%), and its diagnosis is challenging due to the limited accuracy of initial studies. Endoscopic retrograde cholangiopancreatography (ERCP), the gold standard, is invasive and carries risks; therefore, predictive tools are needed to optimize patient selection.
Objective. To compare the diagnostic performance of the 2019 ASGE criteria versus the Calculator *Ignacio Morones Prieto* (C-IMP) predictive model for identifying choledocholithiasis in patients undergoing ERCP at a tertiary care hospital.
Subjects and methods. A retrospective, cross-sectional, single-center study was conducted, including patients undergoing ERCP at the *Hospital Regional de Alta Especialidad Dr. Ignacio Morones Prieto* between January 2022 and December 2024. Clinical, biochemical, and imaging variables were analyzed, as well as the risk classification according to the 2019 ASGE criteria and the probability estimated by the C-IMP. The presence of choledocholithiasis confirmed by ERCP was used as the reference standard. Sensitivity, specificity, predictive values, and ROC curves were calculated for both models.
Results. Seventy-two patients were included, of whom 49 (68.1%) had choledocholithiasis. Cholangitis was significantly associated with its presence, while pancreatitis was more frequent in patients without stones. The common bile duct diameter and the probability estimated by the C-IMP were greater in patients with choledocholithiasis. The ASGE model showed a sensitivity of 73.5%, a specificity of 43.5%, a positive predictive value of 73.5%, and a negative predictive value of 43.5% (AUC 0.59). The C-IMP model showed a sensitivity of 75.5%, a specificity of 82.6%, a positive predictive value of 90.2%, and a negative predictive value of 61.3% (AUC 0.82), with better reclassification and a lower proportion of false positives.
Conclusions. The 2019 ASGE criteria showed limited discriminatory capacity. The C-IMP model demonstrated better diagnostic performance and could optimize the selection of patients eligible for ERCP, reducing unnecessary procedures.

Keywords: ERCP, choledocholithiasis, ASGE, C-IMP.

INTRODUCTION

Choledocholithiasis, characterized by the presence of stones in the common bile duct (CBD), is a common complication of cholelithiasis, with a prevalence of 10-20% in patients with symptomatic gallstones [1,2]. It can lead to serious complications such as obstructive jaundice, ascending cholangitis, or biliary pancreatitis, with a mortality rate of 3-5% in severe cases [5]. In Mexico, factors such as obesity, high-fat diets, and genetic predisposition increase the incidence of biliary diseases, underscoring their clinical importance [1].

The diagnosis of choledocholithiasis is complex due to nonspecific abnormalities in liver function tests and the limited sensitivity of abdominal ultrasound (20-80%), the latter influenced by the operator's experience and the distal location of the stones [2,3,6]. Endoscopic retrograde cholangiopancreatography (ERCP) is the gold standard for diagnosis and treatment, allowing for stone removal and management of biliary obstructions [7]. However, its invasive nature carries risks such as post-ERCP pancreatitis (5-15%), hemorrhage (1-2%), and perforation (0.6%), highlighting the need for careful patient selection to avoid unnecessary procedures [2,5].

Driven by this need, risk stratification systems have been developed to optimize the indication for ERCP. The American Society for Gastrointestinal Endoscopy (ASGE) has classified the predictors that modulate risk stratification. In 2010, it established "very strong," "strong," and "moderate" predictors (see Table 1) [8], although its accuracy has been limited, with sensitivities of 47-75%, specificities of 73-83%, and negative ERCP rates as high as 20-53% [2,5]. In the context of acute cholecystitis, the high-probability

score has a sensitivity of 89% but a low positive predictive value (PPV) (52% vs. 71-79% in the general population), resulting in 39.3% unnecessary ERCPs, suggesting the need for prior tests such as magnetic resonance cholangiopancreatography (MRCP) or endoscopic ultrasound (EUS) [3,9]. In 2019, the ASGE updated its criteria to include "high-probability" and "intermediate-probability" predictors (see Table 1), removing factors such as pancreatitis and a bilirubin level between 1.8-4 mg/dL due to their low performance [5].

Table 1. ASGE predictors for risk stratification for choledocholithiasis, in their 2010 and 2019 versions.

ASGE 2010	ASGE 2019
"Very high" risk factors: Calculus on ultrasound, cholangitis, total bilirubin >4 mg/dL.	**"High probability":** Calculus on CBC imaging, cholangitis, bilirubin >4 mg/dL plus dilated CBC.
"High" risk factors: Bilirubin 1.8–4 mg/dL, dilated CBC >6 mm.	**"Intermediate probability":** Abnormal liver function tests, age >55 years, dilated CBC without bilirubin >4 mg/dL.
"Moderate" risk factors: Abnormal liver function tests, age >55 years, biliary pancreatitis.	

ASGE = American Society for Gastrointestinal Endoscopy; CBC = common bile duct.

Following this update, several studies have emerged seeking to support the change in these predictors and their actual usefulness in optimizing risk stratification and, therefore, reducing unnecessary procedures. Among these studies, Yousaf *et al.* reported a sensitivity of 96.6%, a specificity of 66.7%, and an AUC of 0.81 for ASGE 2019, although negative ERCPs persisted secondary to suboptimal specificity [2]. Similarly, Wang *et al.* demonstrated that some predictors included in ASGE 2019 have high specificity but low sensitivity, limiting their usefulness in ruling out choledocholithiasis [5]. Other studies validated the performance of the ASGE, ESGE, and SAGES criteria in different populations, reporting high sensitivities but variable specificities and the persistence of unnecessary procedures [13-17].

In parallel, several authors have highlighted the role of complementary tools such as MRCP, EUS, and intraoperative exploration of the common bile duct to optimize the diagnostic and therapeutic approach [10,11,17,23,24]. Likewise, alternative predictive models based on clinical, biochemical, and imaging variables have been developed, including simplified scoring systems and models applied to specific contexts, with discriminative capabilities comparable to or better than ASGE 2019 [18-20]. More recently, machine learning-based studies have reported superior diagnostic performance compared to traditional models, demonstrating the potential of these technologies to optimize the prediction of choledocholithiasis [21,22]. Finally, epidemiological and clinical studies have pointed to population variations and limitations of conventional predictors, suggesting that these may overestimate risk in certain clinical scenarios (Table 2) [4,12]. These findings reinforce the need for predictive tools adapted to specific contexts and highlight the value of integrating diagnostic imaging and predictive models to optimize management.

Table 2. ASGE 2019 Choledocholithiasis Risk Criteria.

Category	Criteria
High risk (>50%)	• Presence of a stone in the common bile duct confirmed by transabdominal ultrasound. • Clinically confirmed ascending cholangitis. • Total bilirubin >4 mg/dL and common bile duct dilation >6 mm (with gallbladder in situ) on ultrasound.
Intermediate risk (10-50%)	• Total bilirubin >4 mg/dL (in isolation). • Common bile duct dilation >6 mm (with gallbladder in situ) on ultrasound. • Abnormal liver function tests (elevated AST, ALT, alkaline phosphatase, or GGT; other than bilirubin >4 mg/dL). • Age >55 years. • Biliary abdominal pain. • Evidence of jaundice.
Low risk (<10%)	• Absence of the above predictors. • Normal liver function tests and ultrasound (without common bile duct dilation).

ASGE = American Society for Gastrointestinal Endoscopy; AST = aspartate aminotransferase; ALT = alanine aminotransferase; GGT = gamma-glutamyl transferase.

In Mexico, a predictive model was developed at the *Hospital Regional de Alta Especialidad Dr. Ignacio Morones Prieto*, based on a cohort of 374 patients and validated in 154. This model, which uses logistic regression with variables such as age, pancreatitis, cholangitis, total bilirubin (log-transformed), and CBC calculation by ultrasound, excluded CBC diameter due to multicollinearity. In validation, it achieved an AUC of 93.81%, with a sensitivity of 80% and a specificity of 87% when the high probability threshold was adjusted to 40%, exceeding the accuracy of ASGE 2010 (<70%) [1]. Compared to ASGE, the Calculator *Ignacio Morones Prieto* (C-IMP) reclassified patients more accurately, reducing false positives. Of 234 patients classified as high-risk by ASGE, only 159 were classified as such by C-IMP, with only 30% of those reclassified as intermediate-risk of having choledocholithiasis [1]. Implemented in an online calculator, this model optimizes patient selection for ERCP in resource-limited settings [1].

The comparison between ASGE 2019 and C-IMP is relevant, as both aim to minimize unnecessary ERCPs, but they differ in approach: ASGE uses categorical criteria, while C-IMP employs a continuous model. Although ASGE 2019 improves specificity compared to 2010, its performance is suboptimal for excluding choledocholithiasis [2], while C-IMP promises greater accuracy in Mexican settings [1]. Validating C-IMP against ASGE 2019 in ERCP patients requires further studies, especially outside of Mexico, justifying local research to optimize management and reduce the burden of invasive procedures. Practically speaking, identifying the most accurate tool will improve patient selection for ERCP in referral hospitals, a procedure that depends on the gastroenterologist's experience and learning curve, thus reducing complications and costs associated with avoidable procedures. From a social perspective, optimizing the management of choledocholithiasis in a country with a high prevalence of biliary diseases will improve the quality of care within the public health system, such as at the *Hospital*

Regional de Alta Especialidad Dr. Ignacio Morones Prieto.

Therefore, this study aims to compare the diagnostic performance of the 2019 ASGE criteria against the C-IMP predictive model for identifying choledocholithiasis in patients undergoing ERCP at a tertiary care hospital, providing evidence to guide clinical decisions, maximizing resources, and benefiting patients with a more accurate diagnosis.

METHODS

- **Study design and subjects**

An observational, analytical, retrospective, and cross-sectional study was conducted, using a cohort of patients from the *Hospital Regional de Alta Especialidad Dr. Ignacio Morones Prieto*, treated between January 1, 2022, and December 31, 2024.

Patients over 18 years of age at the time of ERCP were included. These patients underwent ERCP for clinically suspected or confirmed choledocholithiasis and had complete medical records (including liver function tests with bilirubin and transaminases; abdominal ultrasound report showing the diameter or presence of stones in the common bile duct; relevant clinical history such as pancreatitis, cholangitis, jaundice; and ERCP results indicating the presence or absence of choledocholithiasis).

Patients under 18 years of age, those with an indication for ERCP other than choledocholithiasis, those with incomplete medical records, those with a history of biliary surgery, and those with chronic liver disease or extrahepatic cholestasis unrelated to choledocholithiasis were excluded.

Patients with inconclusive ERCP results, contradictory data, recording errors or duplicate records, and those with failed ERCP were also excluded.

Table 3. Variables analyzed in the study.

Variable	Operational definition	Possible values	Units	Type of variable
Dependent				
Choledocholithiasis	Confirmation of common bile duct stones by ERCP.	Yes / No	Unitless	Dichotomous
Independent				
2019 ASGE Classification	Choledocholithiasis prediction system based on high, intermediate, or low probability criteria, according to the presence of predictors (e.g., stone on CBC, bilirubin >4 mg/dL, cholangitis).	High probability Intermediate probability Low probability	Unitless	Ordinal qualitative
C-IMP	Continuous predictive model for choledocholithiasis based on variables such as age, bilirubin (logarithmic), pancreatitis, and cholangitis, which generates a numerical probability.	0 to 100	Percentage (%)	Ratio quantitative
Control (confounding) variables				
Age	Patient's age at the time of ERCP.	18 to 100	Years	Ratio quantitative
Sex	Patient's biological sex.	Masculine Femenine	Unitless	Nominal qualitative
Cholangitis	Diagnosis of cholangitis based on the 2018 Tokyo criteria.	Yes / No	Unitless	Dichotomous
Post-ERCP pancreatitis	Diagnosis of acute pancreatitis following ERCP, documented in the medical record within 7 days of the procedure, based on clinical criteria (abdominal pain, elevated amylase/lipase >3 times the upper limit of normal) or medical confirmation.	Yes / No	Unitless	Dichotomous
ERCP-related bleeding	Bleeding attributable to ERCP (sphincterotomy, hematoma) documented in the medical record within 7 days of the procedure.	Yes / No	Unitless	Dichotomous

Continuation

Perforation	Perforation of the bile duct, duodenum, or other ERCP-related structure, documented in the medical record within 7 days of the procedure, identified by imaging or surgical intervention.	Yes / No	Unitless	Dichotomous

ERCP = endoscopic retrograde cholangiopancreatography; ASGE = American Society for Gastrointestinal Endoscopy; CBC = common bile duct; C-IMP = Calculator Ignacio Morones Prieto.

- **Statistical analysis**

Data processing and analysis were performed using IBM SPSS Statistics software (IBM Corp., Armonk, NY, USA). Qualitative variables were expressed as absolute frequencies and proportions, while quantitative variables were described using measures of central tendency and dispersion (Table 3).

The comparison of qualitative variables between groups with and without choledocholithiasis confirmed by ERCP was performed using Pearson's chi-square test or Fisher's exact test, depending on the expected frequency size. For quantitative variables, those with a normal distribution were compared using Student's t-test for independent samples, while variables with a non-normal distribution were analyzed using the Mann-Whitney U test.

The evaluation of the diagnostic performance of the 2019 ASGE classification and the C-IMP was performed using ERCP confirmation of choledocholithiasis as the reference standard. For each model, sensitivity, specificity, positive predictive value, and negative predictive value were estimated using 2×2 contingency tables.

Additionally, receiver operating characteristic (ROC) curves were generated for both models to analyze their overall discriminative capacity. The area under the curve (AUC) was calculated along with its 95% confidence interval, standard error, and statistical significance level. Diagnostic performance was compared descriptively using AUC values, with values closer to 1 indicating greater discriminative capacity. A significance level of $p < 0.05$ was established for all statistical tests. The results are presented in tables and figures to facilitate interpretation.

- **Ethical considerations**

The research rigorously adhered to the ethical principles of the Declaration of Helsinki (2013, revised in 2024) and current Mexican regulations. Data protection was guaranteed, ensuring that the use of information from medical records did not allow for patient identification, in compliance with the General Law on the Protection of Personal Data Held by Obligated Entities.

The study was considered low-risk, as it used data from medical records retrospectively, in accordance with Article 17, Section I of the Regulations of the General Health Law on Health Research, and obtained permission from the health institution that holds the records, pursuant to NOM-004-SSA3-2012.

The protocol was evaluated and approved by the Research Committee registered with COFEPRIS 17 CI 24 028 093, and by the Research Ethics Committee registered with CONBIOÉTICA-24-CEI-001-20160427, in accordance with NOM-012-SSA3-2012 and NOM-168-SSA1-1998.

RESULTS

During the period from January 1, 2022 to December 31, 2024, a total of 116 ERCPs were performed at the *Hospital Regional de Alta Especialidad Dr. Ignacio Morones Prieto*, of which 44 records were excluded following the established criteria, leaving a total of 72 patients included in the study (see Figure 1).

The median age of the study population was 45.5 years [IQR: 29.25-65.75], with 72.2% (n = 52) being female.

The age distribution was comparable between the groups, with mean ages of 44.4 (±20.4) and 47 (10-84) for patients without choledocholithiasis and with choledocholithiasis confirmed by ERCP, respectively ($p = 0.38$).

There were no significant differences in the sex distribution between the groups ($p = 0.82$).

A higher frequency of cholangitis was observed in patients with confirmed choledocholithiasis ($p = 0.29$), as well as a lower frequency of pancreatitis ($p = 0.12$). There was no significant difference in the presence of stones in the common bile duct as demonstrated by ultrasound, ASGE classification, or complications between the two groups.

It is worth noting that more than half of the patients without choledocholithiasis were classified as being at high risk for choledocholithiasis (see Table 4).

In the group with confirmed choledocholithiasis, a larger common bile duct diameter ($p < 0.05$) and a higher percentage of C-IMP ($p < 0.05$) were observed. No significant differences were observed in age, total bilirubin, and direct bilirubin between the two groups (see Table 5).

Of the 72 patients, 49 (68.1%) were classified as having a high risk of choledocholithiasis, of which 36 (73.5%) had choledocholithiasis confirmed by ERCP. Our study showed a sensitivity of 73.5%, specificity of 43.5%, positive predictive value of 73.5% and negative predictive value of 43.5% for the classification of high risk of choledocholithiasis according to the ASGE (see Table 6).

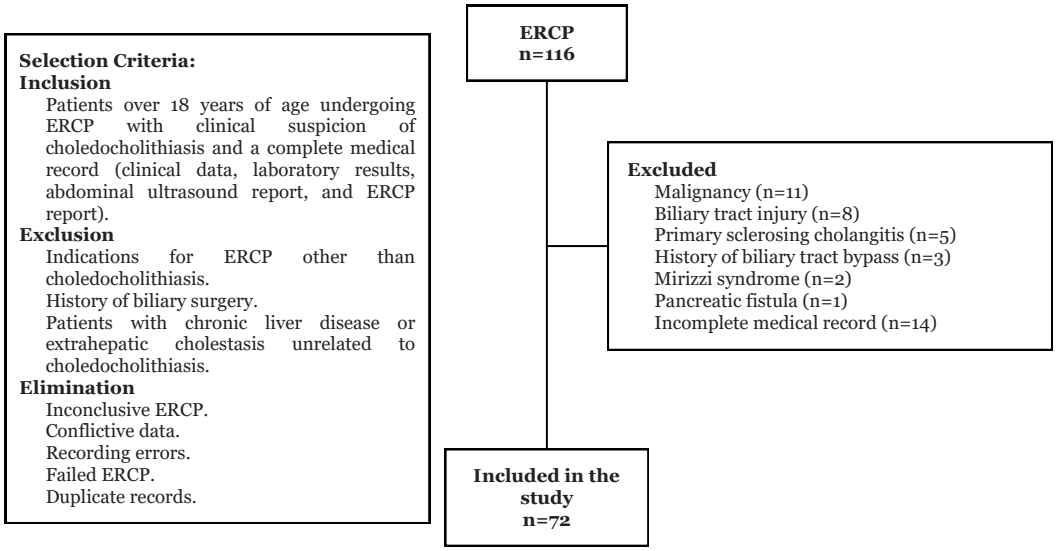


Figure 1. Flowchart for patient selection, with inclusion, exclusion and elimination criteria. *ERCP = endoscopic retrograde cholangiopancreatography.*

Table 4. Analysis of qualitative variables.

Confirmed choledocholithiasis	**No** (n=23)	**Yes** (n=49)	***p value***
Female (%)	17 (73.9%)	35 (71.4%)	.82
Pancreatitis (%)	12 (52.2%)	11 (22.4%)	.012*
Cholangitis (%)	2 (8.7%)	16 (32.6%)	.029*
LCUS (%)	0 (0%)	6 (12.2%)	.09
ASGE (%)			
Low	1 (4.3%)	0	.165
Moderate	9 (39.1%)	13 (26.5%)	
High	13 (56.5%)	36 (73.5%)	
Complications (%)	4 (17.4%)	7 (14.3%)	.48

*The * sign represents statistical significance <.05. LCUS = LCUS: Spanish abbreviation for stone in common bile duct visualized by ultrasound; ASGE = American Society for Gastrointestinal Endoscopy.*

Table 5. Descriptive statistics of the quantitative variables

Confirmed choledocholithiasis	**No** (n=23)	**Yes** (n=49)	***p value***
Age (years)	44.4±20.4	47 (10-84)	.38
Total bilirrubin (mg/dl)	4.2 (2.8-5.6)	5.8 (.4-12.1)	.07
Direct bilirrubin (mg/dl)	3±1.9	4.3 (.1-9.4)	.09
Common bile duct diameter (mm)	6 (4-8)	10.1±4.4	.05*
C-IMP	33.9±20.4	71.7(26.6-116.8)	.05*

*The * sign represents statistical significance <.05. C-IMP = Calculator Ignacio Morones Prieto.*

Table 6. Comparison of patients with and without choledocholithiasis classified according to ASGE.

ASGE Classification	**Negative choledocholithiasis**	**Confirmed choledocholithiasis**
Moderate n=23 (31.9%)	10 (43.5%)	13 (56.5%)
High n=49 (68.1%)	13 (26.5%)	36 (73.5%)

ASGE = American Society for Gastrointestinal Endoscopy.

On the other hand, using the C-IMP, 41 patients (56.9%) were classified as high risk of choledocholithiasis (>50%) of which 37 (90.2%) had the presence of choledocholithiasis confirmed. This represents a sensitivity of 75.5%, specificity of 82.6%, positive predictive value of 90.2% and negative predictive value of 61.3% for the C-IMP high risk classification of choledocholithiasis (see Table 7). Taking this into account, of 49 patients who had been classified as high risk of choledocholithiasis by the ASGE, only 37 of them were reclassified as high risk by the C-IMP (see Table 8).

A ROC curve was performed for the ASGE criteria, obtaining an area under the curve of 0.59, with a standard error of .074 (95% CI: .445-.736; p= .218), indicative of a limited discriminative capacity of the ASGE criteria to identify choledocholithiasis in this population group.

In contrast, the area under the curve for the C-IMP was .82 with a standard error of .048 (95% CI: .73-.92; p <0.001), indicative of a good discriminative capacity of the model to identify choledocholithiasis (see Figure 2).

Table 7. Comparison of patients with and without choledocholithiasis classified by the C-IMP.

C-IMP	Negative choledocholithiasis	Confirmed choledocholithiasis
Moderate n=31 (43.1%)	19 (61.3%)	12 (38.7%)
High n=41 (56.9%)	4 (9.8%)	37 (90.2%)

C-IMP = Calculator Ignacio Morones Prieto.

Table 8. Reclassification to C-IMP of patients with moderate and high risk of choledocholithiasis by the ASGE.

ASGE	Moderate C-IMP	High C-IMP
Moderate n=23	19 (82.6%)	4 (17.4%)
High n=49	12 (24.5%)	37 (75.5%)

ASGE = American Society for Gastrointestinal Endoscopy; C-IMP = Calculator Ignacio Morones Prieto.

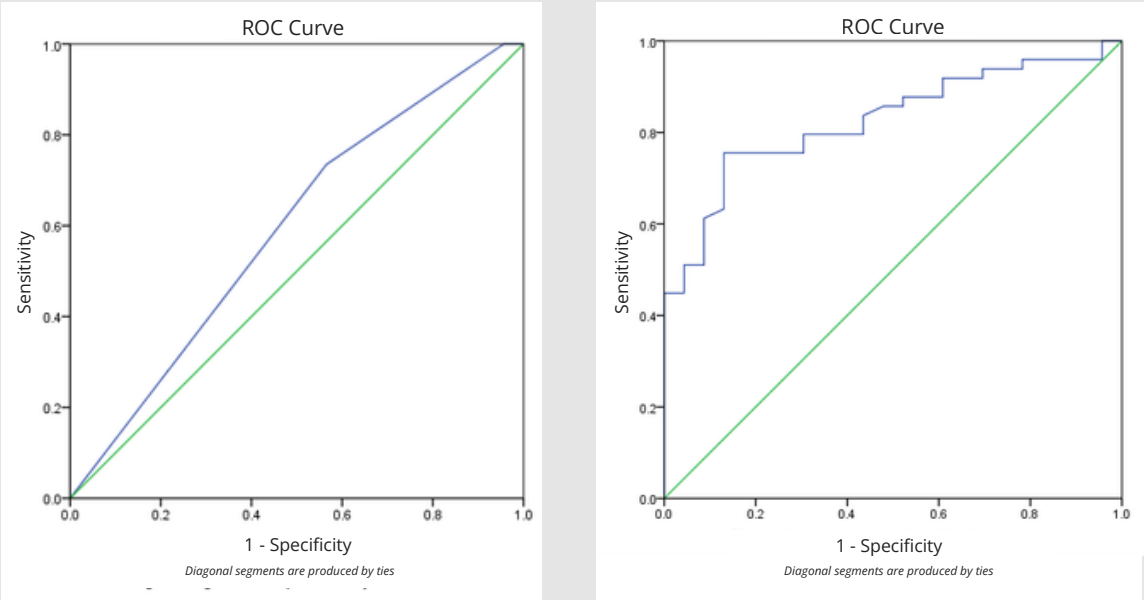


Figure 2. ROC curves for ASGE criteria (left) and C-IMP criteria (right).

DISCUSSION

This study compared the performance of the 2019 ASGE risk stratification criteria for choledocholithiasis with the C-IMP model in a cohort of patients undergoing ERCP at a tertiary care hospital in Mexico. In this population, the ASGE high-risk classification showed limited discriminatory capacity, while the C-IMP model demonstrated superior diagnostic performance, with a better balance between sensitivity and specificity and a reduction in unnecessary ERCP indications.

The prevalence of confirmed choledocholithiasis was high (68.1%), consistent with a population selected for invasive procedures. No differences in age or sex were observed between patients with and without choledocholithiasis, in accordance with the findings reported by Yousaf *et al.* and Hasak *et al.* [2,16], reinforcing the fact that prediction depends primarily on clinical and biochemical variables.

In clinical analysis, cholangitis was significantly associated with the presence of choledocholithiasis, establishing itself as a reliable marker of biliary obstruction. Conversely, pancreatitis was more frequent in patients without common bile duct stones, supporting its limited value as a predictor and its exclusion from the 2019 ASGE criteria [5,14].

From a biochemical standpoint, although bilirubin showed a trend toward higher values in patients with choledocholithiasis, this did not reach statistical significance, confirming its limited diagnostic value when used in isolation [1]. In contrast, the common bile duct diameter was significantly larger in patients with choledocholithiasis, reaffirming its usefulness as an anatomical predictor of biliary obstruction, with high specificity but variable sensitivity [5].

The ASGE score performed suboptimally. Although 68.1% of patients were classified as high-risk, only 73.5% had confirmed choledocholithiasis, resulting in low specificity (43.5%) and a significant proportion of false positives. These findings are consistent with international reports [2,16] and highlight the risk of over-prescribing ERCP when categorical criteria are used in populations with different clinical characteristics.

In contrast, the C-IMP model demonstrated better diagnostic performance. With a cutoff point >50%, it achieved a specificity of 82.6% and a positive predictive value of 90.2%, with sensitivity comparable to ASGE, allowing for more accurate reclassification and a significant reduction in false positives. Importantly, of the 49 patients classified as high-risk by ASGE, only 37 were confirmed by C-IMP, with this subgroup containing the majority of true cases. This behavior is consistent with that described by Huerta-Reyna *et al.* [1].

ROC curve analysis reinforces these findings. The ASGE model showed an AUC of 0.59, indicative of poor discriminative ability and not significantly different from chance, lower than previously reported (~0.80) [2,16]. This discrepancy may be explained by differences in population, sample size, and clinical context, particularly the high proportion of patients with acute cholecystitis and nonspecific biochemical abnormalities [6]. In contrast, the C-IMP model achieved an AUC of 0.82, consistent with its original validation and comparable to other contemporary predictive models, including those based on machine learning [1,21].

From a clinical perspective, ERCP is an effective but not risk-free procedure, making the reduction of unnecessary procedures a priority. In this context, the use of models like C-IMP allows for more precise selection of patients eligible for ERCP, particularly in settings with limited access to MRCP or EUS, favoring decisions based on probability rather than rigid categories.

- **Limitations and perspectives**

This study has inherent limitations due to its retrospective, single-center design and limited sample size, which may affect the generalizability of the results. The exclusive inclusion of patients undergoing ERCP results in a cohort with a high clinical suspicion, which explains the high prevalence observed and may influence the predictive values.

The small sample size limits the precision of the estimates and the analysis by clinical subgroups. Furthermore, the use of ERCP as the gold standard may lead to false negatives due to spontaneous stone migration. Stepwise diagnostic strategies using non-invasive methods, other potentially relevant biochemical markers, and interobserver variability in common bile duct diameter measurements were not evaluated.

Despite these limitations, the results open up important avenues for research. Prospective, multicenter studies are needed to validate the performance of the C-IMP model in different clinical settings and populations, as well as to evaluate its cost-effectiveness. Furthermore, its integration into diagnostic algorithms that incorporate MRCP or EUS could further optimize patient selection for ERCP. Finally, the development of dynamic predictive models based on machine learning represents an opportunity to improve diagnostic accuracy and move towards a more personalized approach.

CONCLUSIONS

The 2019 ASGE criteria remain a widely used tool for the initial stratification of patients with suspected choledocholithiasis; however, in the analyzed population, they showed limited discriminatory capacity, with a significant proportion of false positives and potential over-indication of ERCP. In contrast, the C-IMP model demonstrated a better balance between sensitivity and specificity, as well as a greater capacity to identify patients with a high probability of confirmed choledocholithiasis.

These findings suggest that continuous predictive models based on clinical, biochemical, and imaging variables could represent a more accurate alternative to traditional categorical systems, particularly in populations with clinical characteristics different from

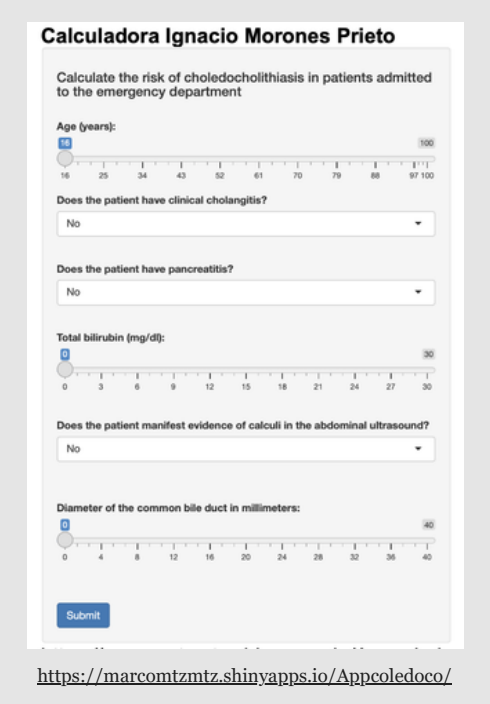
those in which the international guidelines were developed. The ability of C-IMP to reclassify patients initially considered high-risk by ASGE highlights its potential utility for optimizing the selection of ERCP candidates and reducing unnecessary procedures associated with morbidity, costs, and hospital resource utilization.

Furthermore, the observed results support the importance of developing and validating diagnostic tools adapted to the local context, especially in settings where access to complementary methods such as MRCP or EUS may be limited. In this regard, the integration of dynamic predictive models within stepwise diagnostic algorithms could contribute to more individualized and efficient decision-making.

While these results are promising, prospective, multicenter studies with larger sample sizes are needed to confirm the model's performance in different clinical scenarios, evaluate its reproducibility, and determine its impact on clinical outcomes, cost-effectiveness, and the reduction of unnecessary ERCPs.

APPENDICES

Appendix 1. Calculator Dr. Ignacio Morones Prieto (C-IMP)



https://marcomtzmtz.shinyapps.io/Appcoledoco/

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Conflict of interest

The authors declare no conflicts of interest.

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki (2013, revised in 2024) and current Mexican regulations on health research. This was a risk-free study using information from clinical records retrospectively, guaranteeing the confidentiality and anonymization of the data in compliance with the General Law on the Protection of Personal Data Held by Obligated Entities and NOM-004-SSA3-2012. The protocol was approved by the Research Committee with COFEPRIS registration 17 CI 24 028 093 and by the Research Ethics Committee with CONBIOÉTICA registration-24-CEI-001-20160427, in accordance with NOM-012-SSA3-2012 and NOM-168-SSA1-1998.

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