Research Square

Preprints are preliminary reports that have not undergone peer review. They should not be considered conclusive, used to inform clinical practice, or referenced by the media as validated information.

Safety and Efficacy of Peroral Cholangioscopy (POC) During Index ERCP for Patients with Indeterminate Hilar Strictures

Muhammad Saad Faisal
Henry Ford Hospital
Muhammad Salman Faisal
University of South Dakota
Jonathan Montrose
Henry Ford Hospital
Glenn Seela
gseela1@hfhs.org

Henry Ford Hospital
Muhammad Shahzil
Virginia Commonwealth University
Mujtaba Moazzam
Corewell Health
Razan Aburumman
Henry Ford Hospital
Ammad Chaudhary
Henry Ford Hospital
Sumit Singla
Henry Ford Hospital

Research Article

Keywords: Cholangiocarcinoma, Diagnostic accuracy, Tissue acquisition, Pancreaticobiliary Endoscopy, Socioeconomic

Posted Date: September 25th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-11021095/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License

Additional Declarations: Competing interest reported. Dr. Singla serves as a consultant for Boston Scientific

Abstract

Background and Aims

Indeterminate hilar biliary strictures present a diagnostic and therapeutic challenge, given limited guidelines for this indication. Endoscopic Retrograde Cholangiopancreatography (ERCP) is used for sampling and management; though its low yield may delay diagnosis. Peroral Cholangioscopy (POC) offers direct visualization and targeted biopsies, however, concerns remain about adverse events associated with increased instrumentation during the index procedure. We evaluated the safety, efficacy, and adverse events of POC during index ERCP for the diagnosis and management of hilar strictures compared to standard ERCP.

Methods

We conducted a retrospective cohort study of patients undergoing ERCP for indeterminate hilar strictures at a tertiary center between January 2018 and December 2024. Patients were grouped based on the use of POC (SpyGlass™ system) during index ERCP versus standard ERCP alone. The primary outcome was time to diagnosis. Secondary outcomes included time to treatment initiation and adverse events.

Results

117 patients were included (POC, n = 65; standard ERCP, n = 52), with no significant differences in baseline characteristics. Diagnostic yield on index ERCP was higher in the POC group (81% vs. 43%). POC demonstrated greater sensitivity (84.4% vs. 52.9%, p = 0.0051), negative predictive value (69.6% vs. 23.8%, p = 0.0063), and overall diagnostic accuracy (88.5% vs. 59.0%, p = 0.0015). Mean time to diagnosis was shorter with POC (8.8 ± 22.8 days vs. 37.1 ± 100.7 days, p = 0.04). Adverse event rates were not significantly different between groups.

Conclusions

In patients with indeterminate hilar biliary strictures, POC performed during index ERCP significantly improves diagnostic accuracy and reduces time to diagnosis without increasing overall adverse events. Incorporation of POC during initial ERCP may expedite clinical decision-making in this high-risk population.

1. Introduction

Biliary strictures of indeterminate etiology pose a significant diagnostic and therapeutic challenge. These strictures are often malignant, with studies reporting up to 70% being of malignant etiology. [1, 2]

As such, accurate and timely diagnosis of these strictures is crucial for clinical decision making and further management. Guidelines for the diagnosis of indeterminate biliary strictures are limited by the low quality of available evidence, providing conditional recommendations for various approaches and instruments used for diagnosis, evaluation, and management [3, 4]. This limitation is particularly evident in guiding the approach to hilar strictures, as studies have reported an increased risk of cholangitis and bacteremia as a result of biliary instrumentation [3, 5].

Endoscopic approaches are the cornerstone in the evaluation of biliary strictures, allowing for both diagnostic sampling and therapeutic intervention [2]. Various techniques are described in the literature. However, standard ERCP (endoscopic retrograde cholangiopancreatography) techniques, including brush cytology and forceps biopsies, have a relatively low diagnostic yield, often necessitating multiple procedures before a conclusive diagnosis is reached [6]. This delay in diagnosis may contribute to disease progression and negatively impact patient outcomes and satisfaction.

Peroral Cholangioscopy (POC) has emerged as a widely available endoscopic modality offering direct visualization of the biliary tree, enabling targeted biopsies to potentially improve diagnostic accuracy [7]. Despite its advantages, POC involves additional instrumentation and instillation of saline or water during ERCP, raising concerns about potential adverse events, including post-procedural pancreatitis, bleeding, and cholangitis [8]. Given these uncertainties, the role of POC in the initial evaluation of hilar biliary strictures remains a subject of active debate [3].

This study aims to assess the safety, efficacy, and adverse event profile of POC when used during the index ERCP for the diagnosis and management of indeterminate hilar biliary strictures. Specifically, we compare outcomes between patients who underwent ERCP with POC and those who underwent standard ERCP alone, focusing on time to diagnosis, time to treatment initiation, and the incidence of adverse events. By evaluating these parameters, we seek to clarify the utility of POC in optimizing the diagnostic and therapeutic approach for patients with indeterminate hilar strictures.

2. Methods

2.1 Study Design and Settings

This was a retrospective cohort study conducted at a single-center tertiary referral center with advanced endoscopy services. Institutional Review Board (IRB) approval was obtained prior to initiation of data collection and analysis. All procedures were performed by experienced endoscopists with formal training in advanced biliary interventions. Histopathological specimens were reviewed by board-certified pathologists.

2.2 Patient Selection

We reviewed the electronic medical records of all patients who underwent ERCP for indeterminate hilar biliary strictures between January 1, 2018, and December 31, 2024. Indeterminate strictures were

defined as hilar biliary strictures without a definitive diagnosis after initial imaging and laboratory evaluation, requiring tissue sampling or further diagnostic workup. Patients with a known diagnosis of malignancy prior to ERCP (e.g., biopsy-proven malignancy or confirmed benign etiology), inadequate documentation, or previous biliary intervention were excluded.

2.3 Study Groups

Patients were divided into two groups based on whether peroral cholangioscopy (POC) was used during the index ERCP. The case group included patients who underwent ERCP with POC, utilizing digital single-operator cholangioscopy (SpyGlass™ system). The control group included patients who underwent standard ERCP without POC.

2.4 Data Collection

Demographic and clinical data were collected, including age, sex, ethnicity, comorbidities, and imaging findings. Procedural data included type and classification of stricture (according to the Bismuth classification[9]), method of tissue acquisition (e.g., brush cytology, forceps biopsy), adverse events (defined by ASGE lexicon criteria [8]), and follow-up information.

2.5 Outcomes

The primary outcome was time to definitive diagnosis, defined as the interval in days between the index ERCP and establishment of a diagnosis. Secondary outcomes included time to treatment initiation (surgery, chemotherapy, radiation, or palliative care) and incidence of adverse events, including post-ERCP pancreatitis, bleeding, cholangitis, or perforation.

2.6 Statistical Analysis

Descriptive statistics were reported as mean ± standard deviation for continuous variables and frequencies with percentages for categorical variables. Comparisons between the two groups were performed using the t-test for continuous variables and Chi-square or Fisher’s exact test for categorical variables, as appropriate. A two-tailed p-value of < 0.05 was considered statistically significant. All analyses were performed using SPSS Statistics version 29 (IBM Corp., Armonk, NY).

3. Results

A total of 117 patients underwent ERCP for indeterminate hilar biliary strictures between January 2018 and December 2024. Of these, 65 patients (55.5%) underwent ERCP with POC during the index procedure (POC group), while 52 patients (44.4%) underwent standard ERCP alone (control group).

3.1 Baseline Characteristics

There were no statistically significant differences between the two groups in terms of age (POC: 64.56 ± 14.2 years vs. control: 66.06 ± 14.0 years; $p = 0.57$), gender (female: 32.3% vs. 38.5%; $p = 0.49$), race ($p = 0.70$), history of primary sclerosing cholangitis (PSC) (13.8% vs. 15.4%; $p = 0.81$), or anticoagulation use

(9.2% vs. 7.7%; p = 0.70). Bismuth classification of strictures was similarly distributed between the two groups (p = 0.99). Stents were placed in nearly all patients (POC: 96.9% vs. control: 98.1%; p = 1.00) (Table 1).

3.2 Adverse Events

There was no significant difference in the overall complication rates between the two groups (p = 0.15). In the POC group, 3 patients (4.6%) developed post-ERCP pancreatitis compared to none in the control group. Bleeding occurred in 2 patients in each group (3.1% vs. 3.8%). Cholangitis was observed less frequently in the POC group (1.5%) compared to the control group (9.6%) (Table 2).

3.3 Diagnostic Accuracy

A significantly higher proportion of patients in the POC group had positive pathology for malignancy on index ERCP (58.5% vs. 34.6%; p = 0.005). While the overall rate of eventual malignant diagnosis was not significantly different (72.3% vs. 80.8%; p = 0.29), the diagnostic yield of index ERCP was substantially higher in the POC group (81% vs. 43%). The sensitivity of POC was significantly higher than that of standard ERCP (84.4% vs. 52.9%, p = 0.0051). Both modalities demonstrated 100% specificity and positive predictive value (PPV), and thus, statistical comparisons for these metrics were not applicable. However, the negative predictive value (NPV) was significantly greater in the POC group compared to standard ERCP (69.6% vs. 23.8%, p = 0.0063). Overall diagnostic accuracy was also significantly higher in the POC group (88.5% vs. 59.0%, p = 0.0015), reflecting a larger proportion of patients correctly diagnosed during the index procedure. (Table 3)

Sampling techniques differed between groups. In the POC group, 87.7% of patients underwent sampling by biliary brushing combined with cholangioscopy-directed biopsies, 6.2% underwent sampling by intraductal forceps biopsy without cholangioscopic assistance, and 6.2% had brushing alone. In contrast, the control group primarily underwent sampling by brushing (71.2%) or brushing with intraductal forceps biopsies (28.8%) (Table 4).

3.4 Time to Diagnosis and Treatment

The mean time from index ERCP to diagnosis was significantly shorter in the POC group (8.82 ± 22.8 days) compared to the control group (37.10 ± 100.7 days; p = 0.04). Although not statistically significant, the mean time to initiation of treatment was shorter in the POC group (72.17 ± 71.8 days) compared to the control group (130.77 ± 185.3 days; p = 0.06) (Table 3).

4. Discussion

The results of our study highlight the potential clinical utility of incorporating Peroral Cholangioscopy during index ERCP in the evaluation of indeterminate hilar biliary strictures. Our findings demonstrate that using POC significantly shortens time to diagnosis without a corresponding increase in adverse events, suggesting that the enhanced diagnostic accuracy afforded by direct visualization and targeted tissue acquisition does not come at the cost of procedural safety.

Conventional ERCP, combined with standard brush cytology and forceps biopsy, remains the most widely used technique for diagnosing indeterminate biliary strictures, but its diagnostic sensitivity is limited [10]. In a meta-analysis of 16 studies involving 1,556 patients, the overall sensitivity of conventional cytology obtained during ERCP was reported to be 41.6% (99% CI: 38.4%–44.8%), with a negative predictive value of 58.0% (99% CI: 54.8%–61.2%) [11]. These findings are supported by the study from Navaneethan et al., demonstrating limited diagnostic accuracy of combined brush cytology and intraductal biopsy using standard ERCP [12]. This low diagnostic accuracy can prolong the workup, necessitate repeat procedures, and delay critical staging evaluations [3]. Early diagnosis can also prevent unnecessary surgical interventions and significantly improve patient outcomes [13].

To overcome the limitations of conventional ERCP, cholangioscopy has emerged as a valuable diagnostic tool, enhancing the accuracy of diagnosis and enabling targeted biopsies [13, 14]. POC-guided biopsy offers the advantage of targeted tissue acquisition for histopathologic evaluation. A systematic review and meta-analysis of 10 studies assessing the diagnostic performance of POC-guided biopsy for malignant biliary strictures reported a pooled sensitivity of 60.1% (95% CI: 54.9%–65.2%) and a specificity of 98.0% (95% CI: 96.0%–99.0%) [12]. Our study reaffirms these findings, with a higher sensitivity and accuracy with the use of POC during ERCP, even on the index procedure. In addition to facilitating tissue sampling, POC also allows for optimal visual assessment of intraductal lesions. Certain cholangioscopic features, such as neovascularization, mucosal irregularities, surface projections, and intraductal nodules, can raise a strong suspicion for malignancy in the appropriate clinical context [15–17]. In the setting of such cholangioscopic findings and negative histopathologic results, the physician can be more confident in resampling at an earlier interval, given the higher suspicion for malignancy.

Despite higher diagnostic accuracy, some experts suggest avoiding POC on index ERCP where adequate proximal biliary drainage is uncertain due to the increased risk of infection, as demonstrated by some literature [5]. Thus, despite higher sensitivity and accuracy, the use of POC in index ERCP, specifically for hilar strictures, is debated and operator-dependent. This is supported by a large retrospective study by Sethi et al., which compared 3,475 patients undergoing ERCP alone with 402 patients undergoing cholangioscopy. Approximately 30% of each group had biliary strictures. The cholangioscopy group demonstrated a significantly higher overall adverse event rate (7% vs. 2.9%; OR 2.5; 95% CI: 1.56–3.89), primarily driven by an increased incidence of cholangitis (1.0% vs. 0.2%; OR 4.98; 95% CI: 1.06–19.67), while pancreatitis and perforation rate were not significantly different [18]. In contrast, our cohort demonstrated no difference in overall complications, including cholangitis, between the two groups. This is important, since the risk of infection is the primary reason cholangioscopy is avoided for indeterminate hilar strictures on the initial ERCP. This difference can be explained by different instruments used and advancements in techniques since 2011, since more than 90% of POCs performed in Sethi et al. were by conventional cholangioscopy compared to all procedures in our system being performed by catheter based cholangioscope system. Notably, Turowski et al. found that the risk of cholangitis was significantly lower among patients who received prophylactic antibiotics compared to those who did not prior to POC (1% vs. 12.8%, $p < 0.001$) [19]. Therefore, the use of prophylactic

antibiotics and confirmation of adequate biliary drainage are strongly recommended in all patients undergoing cholangioscopy to minimize procedure-related infections [7]. All the patients in our study received prophylactic intravenous antibiotics

With no overall increase in adverse events observed, our study highlights that the incorporation of POC during index ERCP is not only safe but also clinically impactful, as it significantly reduces the time to histopathologic diagnosis in patients with indeterminate hilar strictures. This finding is of particular importance given the aggressive nature and poor prognosis associated with hilar malignancies [20, 21]. Surgical resection remains the only potentially curative option for these tumors [22]. However, the feasibility of curative surgery is often limited by delayed diagnosis, as many patients present with advanced disease and occult metastasis by the time tissue confirmation is achieved through conventional diagnostic pathways. Beyond surgical considerations, early and accurate diagnosis also plays a pivotal role in the initiation of systemic therapies or palliative interventions. Given the significant morbidity and mortality associated with hilar malignancies, timely establishment of malignancy through high-yield diagnostic modalities is essential for appropriate oncologic referral and treatment planning [23]. For instance, patients with confirmed unresectable disease may benefit from earlier initiation of chemotherapy, locoregional therapy, or biliary stenting to alleviate symptoms and prevent complications [24].

Although our study demonstrated a numerical trend toward reduced time to treatment initiation, this difference did not reach statistical significance. Similar trends have been noted in prior literature. Notably, patients with early-stage disease often experience delays in treatment initiation due to the need for comprehensive diagnostic evaluation, multidisciplinary team discussions, and complex treatment planning. In contrast, management of advanced-stage disease is typically more straightforward, often requiring fewer deliberations and being directed by a single specialist [25]. Additionally, patients with advanced disease may present with more pronounced symptoms, creating a greater sense of urgency that accelerates therapeutic decision-making. These observations highlight potential confounding factors and underscore the importance of structured follow-up protocols to ensure timely interventions [23].

5. Limitations

Despite its advantages, this study has several limitations. As a retrospective analysis, it is inherently limited by potential selection bias, unmeasured confounding variables, and reliance on the accuracy of documentation in medical records. Additionally, the sample size, while adequate for preliminary conclusions, limits the power to detect differences in less common adverse events. The study was also conducted within a single healthcare system, which may affect the generalizability of the findings to other settings or patient populations. Variability in operator experience and technique, as well as non-standardized criteria for biopsy selection, may have influenced diagnostic yield and outcomes.

6. Conclusion

Our findings demonstrate that the use of POC during index ERCP for patients with indeterminate hilar biliary strictures is both safe and clinically beneficial. POC was associated with a significantly shorter time to diagnosis and higher tissue diagnostic yield, without an increase in overall adverse events compared to standard ERCP. These results support the integration of POC into the diagnostic workflow for complex hilar biliary strictures and highlight its potential to improve diagnostic efficiency. Future prospective multicenter studies are needed to confirm these results and further evaluate the long-term clinical and cost implications of early POC use.

Declarations

Conflict of Interest Statement

S. Singla: Consultant for Boston Scientific. All other authors declare no financial relationships.

Author Contribution

G.S. and R.A. contributed to the writing and editing of the manuscript and interpretation of the data. J.M. and A.C. contributed to project design and assessment of clinical relevance. M.S. and M.M. contributed to data collection. S.S. oversaw the project and the manuscript. M.SaF. and M.SalF. contributed to data collection, analysis, and manuscript preparation.

Data Availability

The data that support the findings of this study were extracted from patient records in the Epic electronic medical record system at Henry Ford Hospital, but restrictions apply to the availability of these data, which were used under institutional permission for the current study and so are not publicly available. The data are, however, available from the corresponding author upon request and with the permission of Henry Ford Hospital.

References

1. Nabi, Z. and D.N. Reddy, *Multidisciplinary Approach to Indeterminate Biliary Strictures*. Gastrointest Endosc Clin N Am, 2022. 32(3): p. 411–425.
2. Lin, T.Y., et al., *Endoscopic and novel approaches for evaluation of indeterminate biliary strictures*. J Formos Med Assoc, 2025.
3. Fujii-Lau, L.L., et al., *American Society for Gastrointestinal Endoscopy guideline on the role of endoscopy in the diagnosis of malignancy in biliary strictures of undetermined etiology: summary and recommendations*. Gastrointest Endosc, 2023. 98(5): p. 685–693.

4. Yadlapati, S., et al., *Clinical approach to indeterminate biliary strictures: Clinical presentation, diagnosis, and workup*. World J Gastroenterol, 2023. 29(36): p. 5198–5210.
5. Othman, M.O., et al., *A prospective study of the risk of bacteremia in directed cholangioscopic examination of the common bile duct*. Gastrointest Endosc, 2016. 83(1): p. 151–7.
6. McCarty, T.R., et al., *The Role of Artificial Intelligence Combined With Digital Cholangioscopy for Indeterminant and Malignant Biliary Strictures: A Systematic Review and Meta-analysis*. J Clin Gastroenterol, 2025.
7. Angsuwatcharakon, P., et al., *Consensus guidelines on the role of cholangioscopy to diagnose indeterminate biliary stricture*. HPB, 2022. 24(1): p. 17–29.
8. Cotton, P.B., et al., *A lexicon for endoscopic adverse events: report of an ASGE workshop*. Gastrointest Endosc, 2010. 71(3): p. 446–54.
9. Dar, F.S., et al., *National guidelines for the diagnosis and treatment of hilar cholangiocarcinoma*. World J Gastroenterol, 2024. 30(9): p. 1018–1042.
10. Wen, L.J., et al., *Efficacy and Safety of Digital Single-Operator Cholangioscopy in the Diagnosis of Indeterminate Biliary Strictures by Targeted Biopsies: A Systematic Review and Meta-Analysis*. Diagnostics (Basel), 2020. 10(9).
11. Burnett, A.S., T.J. Calvert, and R.J. Chokshi, *Sensitivity of endoscopic retrograde cholangiopancreatography standard cytology: 10-y review of the literature*. J Surg Res, 2013. 184(1): p. 304–11.
12. Navaneethan, U., et al., *Single-operator cholangioscopy and targeted biopsies in the diagnosis of indeterminate biliary strictures: a systematic review*. Gastrointest Endosc, 2015. 82(4): p. 608 – 14.e2.
13. Parsa, N. and M.A. Khashab, *The Role of Peroral Cholangioscopy in Evaluating Indeterminate Biliary Strictures*. Clin Endosc, 2019. 52(6): p. 556–564.
14. Tanisaka, Y. and R. Hawes, *Peroral cholangioscopy: past, present and future*. Clin Endosc, 2025. 58(3): p. 360–369.
15. Seo, D.W., et al., *Cholangioscopic findings in bile duct tumors*. Gastrointest Endosc, 2000. 52(5): p. 630–4.
16. Kim, H.J., et al., *Tumor vessel: a valuable cholangioscopic clue of malignant biliary stricture*. Gastrointest Endosc, 2000. 52(5): p. 635–8.
17. Subhash, A., J.L. Buxbaum, and J.H. Tabibian, *Peroral cholangioscopy: Update on the state-of-the-art*. World J Gastrointest Endosc, 2022. 14(2): p. 63–76.
18. Sethi, A., et al., *ERCP with cholangiopancreatoscopy may be associated with higher rates of complications than ERCP alone: a single-center experience*. Gastrointestinal Endoscopy, 2011. 73(2): p. 251–256.
19. Turowski, F., et al., *Diagnostic and therapeutic single-operator cholangiopancreatoscopy with SpyGlassDS™: results of a multicenter retrospective cohort study*. Surgical Endoscopy, 2018. 32(9): p. 3981–3988.

20. Nghiem, V., et al., *Short- and Long-Term Survival of Metastatic Biliary Tract Cancer in the United States From 2000 to 2018*. Cancer Control, 2023. 30: p. 10732748231211764.
21. Platt, K.D. and A.R. Schulman, *Increasing the Yield: When More Is Better*. Am J Gastroenterol, 2022. 117(5): p. 729–730.
22. Soares, K.C., et al., *Hilar cholangiocarcinoma: diagnosis, treatment options, and management*. Hepatobiliary Surg Nutr, 2014. 3(1): p. 18–34.
23. Kerekes, D.M., et al., *Hepatopancreatobiliary malignancies: time to treatment matters*. J Gastrointest Oncol, 2023. 14(2): p. 833–848.
24. Taghizadeh, H., et al., *Systemic treatment of patients with locally advanced or metastatic cholangiocarcinoma - an Austrian expert consensus statement*. Front Oncol, 2023. 13: p. 1225154.
25. Danese, M.D., et al., *Treatment Patterns and Survival in Locally Advanced or Metastatic Biliary Tract Cancer Using SEER Medicare Data*. Gastro Hep Adv, 2023. 2(4): p. 580–587.

Tables

Table 1. Baseline Characteristics and Procedural Details of Patients Undergoing Index ERCP With and Without POC

Characteristic	ERCP + POC (n = 65)	ERCP Alone (n = 52)	P Value
Age, y (mean ± SD)	64.6 ± 14.2	66.1 ± 14.0	0.57
Female sex, n (%)	21 (32.3)	20 (38.5)	0.49
Race, n (%)			0.70
— White	44 (67.7)	33 (63.5)	
— Black	11 (16.9)	12 (23.1)	
— Other	10 (15.4)	7 (13.5)	
History of PSC, n (%)	9 (13.8)	8 (15.4)	0.81
Anticoagulation use, n (%)	6 (9.2)	4 (7.7)	0.70
Bismuth classification, n (%)			0.99
— I	24 (36.9)	21 (40.4)	
— II	12 (18.5)	10 (19.2)	
— IIIa	4 (6.2)	3 (5.8)	
— IIIb	5 (7.7)	4 (7.7)	
— IV	20 (30.8)	14 (26.9)	
Stent placement, n (%)	63 (96.9)	51 (98.1)	1.00

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; POC, peroral cholangioscopy; PSC, primary sclerosing cholangitis.

Table 2. Adverse Events

Outcome	ERCP + POC (n = 65)	ERCP Alone (n = 52)	P Value
Any adverse event, n (%)	6 (9.2)	7 (13.5)	0.15
Post-ERCP pancreatitis, n (%)	3 (4.6)	0 (0)	
Bleeding, n (%)	2 (3.1)	2 (3.8)	
Cholangitis, n (%)	1 (1.5)	5 (9.6)	

Values are presented as mean ± standard deviation or number (percentage).

Table 3. Diagnostic Performance of Index ERCP With and Without POC

Parameter	ERCP + POC	ERCP Alone	P Value
Eventual Diagnosis of Malignancy, n (%)	47 (72.3)	42 (80.8)	0.29
Positive pathology on index ERCP, n (%)	38 (58.5)	18 (34.6)	0.005
Diagnostic yield of index ERCP, n (%)	38/47 (80.9)	18/42 (42.9)	
Time to diagnosis, d (mean ± SD)	8.8 ± 22.8	37.1 ± 100.7	0.04
Time to treatment initiation, d (mean ± SD)	72.2 ± 71.8	130.8 ± 185.3	0.06
Sensitivity, %	84.4	52.9	0.0051
Specificity, %	100	100	
Positive predictive value, %	100	100	
Negative predictive value, %	69.6	23.8	0.006
Overall accuracy, %	88.5	59.0	0.0015

Table 4. Sampling Techniques Used During Index ERCP

Sampling Method	ERCP + POC (n = 65)	ERCP Alone (n = 52)
Brushings + cholangioscopy-directed biopsy	57 (87.7)	
Intraductal forceps biopsy alone	4 (6.2)	
Brushings alone	4 (6.2)	37 (71.2)
Brushings + intraductal forceps biopsy		15 (28.8)

Values are presented as number (percentage).