

Diagnostic and Therapeutic Impact of SpyGlass DS-Assisted Single-Operator Digital Cholangioscopy During ERCP

Çağrı Bilgiç¹, Erman Sobutay², Salih Bölük¹, Sümeyra Emine Bölük³, Barış Bayraktar¹

¹ Medical Park Gebze Hospital, Department of General Surgery, Kocaeli, Türkiye

² Koç Foundation American Hospital, Department of General Surgery, İstanbul, Türkiye

³ İstanbul Sultan Abdülhamid Han Training and Research Hospital, Department of General Surgery, İstanbul, Türkiye

*Correspondence: Çağrı Bilgiç; drcbilgic@gmail.com

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Abstract

Aim: This study aimed to evaluate the technical success, diagnostic and therapeutic impact, safety profile, and long-term outcomes of SpyGlass DS-assisted single-operator digital cholangioscopy performed concomitantly with endoscopic retrograde cholangiopancreatography (ERCP). **Methods:** A retrospective analysis of 55 consecutive adult patients who underwent SpyGlass DS-assisted cholangioscopy during ERCP at a tertiary referral center between February 2022 and May 2024 was performed. Technical success, additional diagnostic findings, therapeutic outcomes, complications, and long-term outcomes were assessed. **Results:** Cholangioscopy was technically successful in 49 of 55 patients (89.1%). The most common indication was choledocholithiasis (78.2%), followed by evaluation of indeterminate biliary strictures, intraoperative/perioperative biliary assessment, and management of migrated stents. Among the 49 technically successful procedures, cholangioscopy revealed additional clinically relevant findings that altered patient management in 10 patients (20.4%). In 5 patients (10.2%), residual stones were detected despite negative balloon-occlusion cholangiography during ERCP. In two patients (4.0%), intraductal lesions that could not be adequately characterized by fluoroscopic methods were visualized. In three patients, intraoperative or perioperative cholangioscopy contributed directly to surgical decision-making. Post-ERCP pancreatitis occurred in 5 patients (9.1%), all mild. During a median follow-up of 27 months (IQR, 25–35 months), 4 patients (7.3%) required repeat biliary intervention. **Conclusions:** SpyGlass DS-assisted digital cholangioscopy is a valuable adjunct to conventional ERCP, providing a high technical success rate and clinically meaningful diagnostic information beyond that obtained with standard imaging. Its ability to detect residual stones and characterize intraductal lesions may influence patient management, while selected intraoperative applications suggest a promising role in hepatobiliary surgery.

Keywords: Cholangioscopy; SpyGlass DS; ERCP; choledocholithiasis; biliary stricture; single-operator cholangioscopy

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) remains one of the cornerstone interventional procedures for the diagnosis and treatment of choledocholithiasis, biliary strictures, and various pancreatobiliary disorders. However, conventional fluoroscopic imaging and balloon occlusion cholangiography have several well-recognized limitations. Residual common bile duct stones may be missed, particularly in the presence of dilated bile ducts, significant pneumobilia, juxtapapillary diverticula, or stone fragments following intracorporeal lithotripsy. Prospective studies and recent meta-analyses have demonstrated that residual stones can be detected in 11%–30% of patients despite negative balloon occlusion cholangiography.^{1,2} Missed stones are associated with recurrent biliary pain, cholangitis, acute pancreatitis, and the need for repeat intervention.³

Another important limitation of ERCP is encountered in the evaluation of biliary strictures. The diagnostic sensitivity of brush cytology and standard biopsy techniques performed under fluoroscopic guidance remains limited, and diagnostic challenges persist, particularly in patients with indeterminate biliary strictures that are suspicious for malignancy but cannot be adequately characterized using conventional imaging modalities.^{4,5} Recent guidelines have reported that direct intraductal visualization and targeted biopsy sampling in selected cases improve diagnostic accuracy and provide important contributions to patient management.^{4,6}

Peroral cholangioscopy enables direct visualization of the biliary mucosa and lumen, allowing real-time assessment of both residual stones and intraductal lesions.^{7,8} Widespread adoption of cholangioscopy was long limited by the need for a second operator, device fragility, and suboptimal image quality. These limitations were largely overcome with the introduction of the single-operator SpyGlass system in 2007.⁹ Subsequently, the SpyGlass DS™ Direct Visualization System (Boston Scientific Corp., Marlborough, MA, USA) represented a significant technological advancement in cholangioscopy by incorporating fully digital imaging, an approximately 60% wider field of view, four-way tip deflection, and a 1.2-mm working channel that enables biopsy sampling or lithotripsy under direct visualization.^{10,11}

Recent studies have demonstrated high success rates of the SpyGlass DS system in both diagnostic and therapeutic applications. Diagnostic success rates of 96%–99% have been reported for the detection of residual bile duct stones using digital cholangioscopy, while therapeutic success rates ranging from 88% to 96% have been achieved in the management of difficult common bile duct stones with electrohydraulic or laser lithotripsy.^{11–13} In a systematic review and meta-analysis published by Dall'Agnol et al. in 2025, which included 485 procedures, residual stones were detected in 27% of patients despite negative balloon occlusion cholangiography, with the rate increasing to 32% in studies utilizing digital cholangioscopy systems.² These findings suggest that direct intraductal visualization may provide clinically meaningful information beyond that obtained with conventional imaging techniques.

However, the applications of cholangioscopy are no longer limited to stone disease. Evaluation of indeterminate biliary strictures, targeted biopsy sampling, characterization of intraductal neoplasms, management of migrated stents, and intraoperative or perioperative biliary assessment in selected cases have emerged as increasingly important indications for its use.^{4,6,8,14,15} In particular, recent surgical series have demonstrated that SpyGlass technology can also be utilized during laparoscopic or open surgery for the assessment of biliary anatomy and bile duct exploration.^{14,15}

Nevertheless, much of the existing literature has focused on specific indications, and real-world data evaluating the diagnostic and therapeutic impact of digital cholangioscopy across different clinical scenarios remain limited. Furthermore, evidence regarding its integration into surgical practice and its long-term clinical outcomes is still scarce.

The present study aimed to evaluate the clinical characteristics, procedural indications, technical success rates, diagnostic and therapeutic impact, procedure-related complications, and long-term follow-up outcomes of patients who underwent SpyGlass DS-assisted single-operator digital cholangioscopy concomitantly with ERCP at our center over a 52-month period. In addition, we sought to assess the additional clinical value of cholangioscopy beyond conventional techniques and to explore its potential applications in selected intraoperative and perioperative settings.

2. Materials and Methods

2.1. Study Design

This retrospective cohort study was conducted at the Interventional Endoscopy Unit of the Department of General Surgery at a tertiary care referral center. All consecutive adult patients who underwent cholangioscopy using the SpyGlass DS™ Direct Visualization System (Boston Scientific Corp., Marlborough, MA, USA) concomitantly with ERCP between February 2022 and May 2024 were included in the study.

Demographic characteristics, comorbidities, procedural indications, laboratory findings, endoscopic and cholangioscopic findings, therapeutic interventions, procedure-related complications, and follow-up data were retrospectively retrieved from the electronic medical record system. Patients younger than 18 years of age and those with incomplete clinical or procedural data were excluded.

Ethical approval was obtained from the Human Research Ethics Committee of İstinye University İstanbul (decision no.: 2025-373, date: 10.04.2026) in compliance with the Declaration of Helsinki.

2.2. ERCP and cholangioscopy procedure

All procedures were performed by a single endoscopist experienced in pancreatobiliary interventions in an operating room equipped with C-arm fluoroscopy. Patients underwent the procedures under general anesthesia or deep sedation. The attending anesthesiologist selected the anesthesia method based on patient and procedural factors; no study-specific criteria were used.

At our institution, SpyGlass DS-assisted cholangioscopy is routinely performed as part of the standard ERCP protocol in all patients undergoing ERCP; therefore, no additional clinical selection criteria were applied specifically for the use of cholangioscopy. Biliary cannulation was achieved using a standard guidewire-assisted technique. Depending on the indication, endoscopic sphincterotomy, balloon sweeping, basket extraction, mechanical lithotripsy, stent placement, or stent removal was performed.

The SpyGlass DS cholangioscopy system was used following standard ERCP for the detection of residual stones, evaluation and treatment of difficult biliary stones, assessment of biliary anatomy, evaluation of indeterminate biliary strictures, targeted biopsy sampling, or therapeutic interventions under direct visualization. The cholangioscope was advanced through the working channel of the duodenoscope over a guidewire, allowing direct visualization of the biliary tree (Figure 1).

When clinically indicated, cholangioscopy was also used intraoperatively or perioperatively to assist surgical decision-making, assess biliary tract integrity, or directly visualize biliary pathology.

For prophylaxis against post-ERCP pancreatitis, all patients received 100 mg rectal indomethacin before the procedure and periprocedural intravenous hydration. Antibiotic therapy or prophylaxis was administered according to clinical indications.

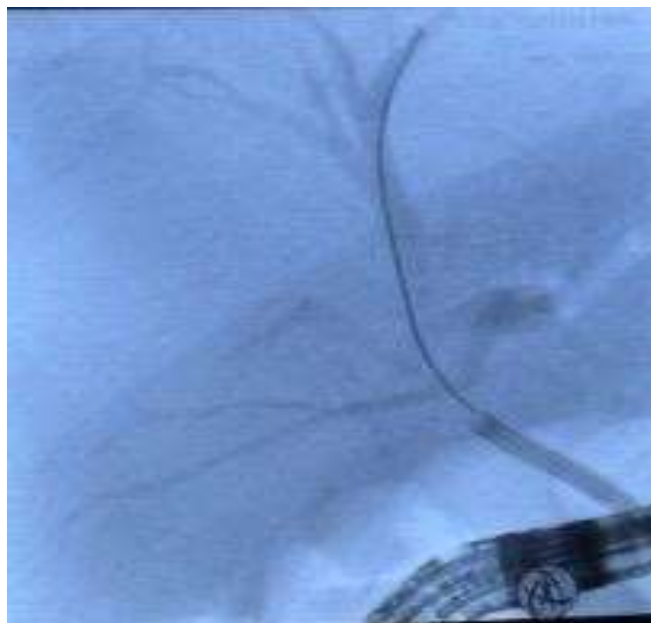


Figure 1. Fluoroscopic image demonstrating advancement of the SpyGlass DS cholangioscope over a guidewire into the biliary tree during ERCP.

2.3. Study Outcomes and Definitions

The primary study endpoint was the technical success of cholangioscopy. Technical success was defined as successful advancement of the SpyGlass DS system to the target biliary segment and acquisition of image quality sufficient for clinical evaluation.

Secondary endpoints included the additional diagnostic contribution of cholangioscopy, the impact of cholangioscopic findings on clinical management, the success of therapeutic interventions, procedure-related complications, and the need for repeat biliary intervention during long-term follow-up.

Additional diagnostic contribution was defined as the identification of findings by cholangioscopy that were not detected by conventional fluoroscopy or balloon occlusion cholangiography and that resulted in a change in patient management.

2.4. Assessment of Complications

Post-ERCP pancreatitis was defined according to the consensus criteria proposed by Cotton et al.¹⁶ New-onset abdominal pain following the procedure accompanied by serum amylase and/or lipase levels at least three times the upper limit of normal and requiring unplanned hospitalization was considered post-ERCP pancreatitis. Severity was classified as mild, moderate, or severe.

Bleeding, perforation, cholangitis, and other procedure-related adverse events were assessed through review of patient records and follow-up data. Intraoperative complications were recorded according to the Satava classification system.¹⁷

2.5. Follow-up

All patients were evaluated through the electronic medical record system and outpatient follow-up records. During long-term follow-up, the need for repeat ERCP, repeat biliary intervention, additional surgical procedures, and the occurrence of biliary complications were recorded. Follow-up duration was calculated from the date of the last clinical evaluation.

2.6. Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean $\pm$

standard deviation or median (minimum–maximum), as appropriate. Categorical variables were expressed as numbers and percentages. As the primary aim of the study was to describe the clinical outcomes of SpyGlass DS-assisted cholangioscopy, analyses were primarily descriptive in nature.

3. Results

3.1. Patient Characteristics and Procedural Indications

A total of 55 patients were included in the study. The mean age was 52.8 ± 16.3 years (range, 24–87), and 29 patients (52.7%) were male. Diabetes mellitus was present in 8 patients (14.5%), cardiovascular comorbidities in 17 (30.9%), and anticoagulant use in 8 (14.5%).

The most common indication for cholangioscopy was choledocholithiasis, accounting for 43 patients (78.2%). Other indications included evaluation of indeterminate biliary strictures ($n=6$, 10.9%), pancreatic duct intervention for retrieval of migrated stents ($n=2$, 3.6%), intraoperative/perioperative biliary assessment ($n=3$, 5.5%), and other pancreatobiliary disorders ($n=1$, 1.8%). Demographic characteristics and preprocedural laboratory findings are presented in Table 1.

Table 1. Patient Characteristics, Procedural Indications, and Preprocedural Laboratory Findings

Characteristic	Value (n=55)
Age, mean $\pm$ SD (years)	52.8 ± 16.3
Male sex, n (%)	29 (52.7)
Diabetes mellitus, n (%)	8 (14.5)
Cardiovascular comorbidity, n (%)	17 (30.9)
Anticoagulant use, n (%)	8 (14.5)
Procedural indication	
Choledocholithiasis, n (%)	43 (78.2)
Evaluation of biliary stricture, n (%)	6 (10.9)
Pancreatic duct intervention, n (%)	2 (3.6)
Intraoperative/perioperative use, n (%)	3 (5.5)
Other pancreatobiliary disorders, n (%)	1 (1.8)
Preprocedural laboratory findings	
Total bilirubin, median (range), mg/dL	3.0 (0.4 - 15.0)
Direct bilirubin, median (range), mg/dL	2.1 (0.1 - 8.2)
Amylase, median (range), U/L	74 (42 - 2497)

3.2. Technical success and procedural findings

Cholangioscopy was technically successful in 49 of 55 patients (89.1%). In four patients, the SpyGlass DS cholangioscope could not be advanced to the target biliary segment. In two of these patients, adequate cannulation could not be achieved because of perampullary polypoid lesions, while in the remaining two, marked distal bile duct edema prevented successful cannulation; consequently, these patients were managed with conventional ERCP alone. In two additional patients, cholangioscopy could be performed; however, image quality was considered suboptimal because of marked inflammatory changes. Procedures were performed under general anesthesia in 51 patients (92.7%) and under deep sedation in 4 patients (7.3%).

Among the 49 technically successful procedures, the common bile duct and hepatic duct bifurcation were visualized in all patients. The cystic duct orifice and pancreatic duct orifice were identified in 33 (67.3%) and 34 (69.4%) patients, respectively. The median duration of ERCP with cholangioscopy was 30 minutes (range, 15–60).

Purulent bile was observed in 5 patients (10.2%) (Figure 2), and inflammatory mucosal changes were identified in 11 patients (22.4%) during cholangioscopy (Figure 3). Sphincterotomy was performed in all technically successful cases, whereas balloon sweeping and biliary stent placement were performed in 44 (89.8%) and 22 patients, respectively. Procedural findings are summarized in Table 2.

Table 2. Procedural Details in Patients Undergoing Successful Cholangioscopy

Parameter	n (%)
Technical success of cholangioscopy	49/55 (89.1)
Procedure duration, median (range), min	30 (15 - 60)
Visualization of the hepatic duct bifurcation*	49/49 (100)
Visualization of the cystic duct orifice*	33/49 (67.3)
Visualization of the pancreatic duct orifice*	34/49 (69.4)
Conventional stone extraction (balloon/basket)	43/49 (78.2)
SpyGlass-guided direct stone extraction	5/49 (10.2)
Holmium laser lithotripsy	1/49 (2.0)
Cholangioscopy-guided biopsy	2/49 (4.1)
Biliary stent placement	22/49 (45.0)
Sphincterotomy performed	49/49 (100)
Balloon sweeping performed	44/49 (89.8)
Purulent bile (cholangitis)	5/49 (10.2)
Intraoperative/perioperative use	3/49 (6.0)

*Calculated among technically successful cholangioscopy procedures (n=49)



Figure 2. Endoscopic view demonstrating purulent bile drainage from the biliary system during ERCP in a patient with acute cholangitis.



Figure 3. Direct intraductal visualization obtained with the SpyGlass DS system demonstrating inflammatory changes of the biliary mucosa.

3.3. Additional Diagnostic and Therapeutic Impact of Cholangioscopy

Among the 49 patients who underwent technically successful cholangioscopy, additional findings that altered clinical management were identified in 10 patients (20.4%).

3.4. Contribution to ERCP

In five patients (10.2%), residual stones that were not detected on balloon occlusion cholangiography during ERCP were directly visualized, allowing additional endoscopic stone extraction (Figure 4). In addition, intraductal lesions that could not be adequately characterized by fluoroscopic imaging were identified in two patients (4.0%). In these cases, cholangioscopy-guided evaluation and targeted biopsy findings led to modification of the diagnostic and therapeutic approach.



Figure 4. Direct visualization and basket extraction of a residual bile duct stone detected by SpyGlass DS cholangioscopy.

3.5. Intraoperative applications

Cholangioscopy was used during the intraoperative or perioperative period in three patients (5.5%). In one patient, intraoperative cholangioscopy was performed to evaluate complex biliary anatomy and assist surgical reconstruction planning. In another patient, the source of a bile leak that developed during surgery for hepatic hydatid disease was directly visualized, enabling primary repair. In the third patient, cholangioscopy was used to confirm ductal integrity following biliary reconstruction. In all cases, cholangioscopic findings contributed to surgical decision-making.

3.6. Complications

Bleeding occurred in one patient (1.8%) during sphincterotomy extension and was successfully controlled using endoscopic techniques without the need for additional intervention.

Post-ERCP pancreatitis developed in 5 patients (9.1%). All cases were mild in severity and resolved with conservative management. One patient who presented with severe acute pancreatitis and biliary sepsis died two days after the procedure due to necrotizing pancreatitis and multiple organ dysfunction syndrome. Given the patient's clinical condition at presentation, this case was not considered procedure-related post-ERCP pancreatitis.

No perforation or bleeding requiring blood transfusion was observed. The 30-day mortality rate was 1.8% (n=1). Complications are summarized in Table 3.

Table 3. Procedure-Related Complications

Parameter	n (%)
Post-ERCP pancreatitis	5/55 (9.1)
Procedural bleeding	1/55 (1.8)
Perforation	0
Bleeding requiring blood transfusion	0
30-day mortality	1/55 (1.8)

3.7. Long-term Follow-up Outcomes

The mean follow-up duration was 30 months, with a median of 27 months (IQR, 25–35 months). During follow-up, four patients (7.3%) required repeat biliary intervention because of recurrent or persistent biliary pathology. One patient was treated with ERCP and stent exchange for recurrent cholangitis. In one patient, distal pancreatectomy and splenectomy were performed because a migrated pancreatic stent could not be removed endoscopically. Another patient underwent repeat SpyGlass-assisted ERCP with biopsy for evaluation of a stricture at the level of the cystic duct. The remaining patient was referred for surgical reconstruction because of an impassable benign biliary stricture. Details of the patients requiring repeat biliary intervention are presented in Table 4.

Table 4. Patients Requiring Repeat Intervention During Long-Term Follow-up

Patient	Reason for Repeat Intervention	Intervention Performed
1	Recurrent cholangitis	ERCP with stent exchange
2	Migrated pancreatic stent	Distal pancreatectomy and splenectomy
3	Biliary stricture/granulation tissue	SpyGlass-assisted ERCP with biopsy
4	Benign biliary stricture	Surgical reconstruction

4. Discussion

In this study, we evaluated the technical success rate, diagnostic and therapeutic impact, safety profile, and long-term clinical outcomes of SpyGlass DS-assisted single-operator digital cholangioscopy performed concomitantly with ERCP. The main findings were an overall technical success rate of 89.1%, identification of additional findings that altered clinical management in 20.4% of patients, detection of residual stones in 10.2% of patients despite negative balloon occlusion cholangiography, and the contribution of intraoperative/perioperative cholangioscopy to surgical decision-making in selected cases. These findings suggest that digital cholangioscopy is not only a valuable tool for the management of difficult biliary stones but also an important adjunct in clinical situations where conventional ERCP may be insufficient.

Digital single-operator cholangioscopy systems enable direct visualization of the biliary lumen and mucosa, thereby overcoming several inherent limitations of fluoroscopic imaging. The clinical use of first-generation cholangioscopy systems remained limited because of the need for two operators, device fragility, and suboptimal image quality. In contrast, the SpyGlass DS system has represented a major technological advancement through the incorporation of digital imaging, an enhanced irrigation system, and four-way tip deflection.^{9-11,18} Reported technical success rates generally range from 90% to 98%, and the 89.1% success rate observed in our series is broadly consistent with these findings.^{10,11,18} Notably, all technical failures in our cohort were attributable to anatomical or pathological factors that prevented advancement of the cholangioscope, including periampullary lesions and marked distal bile duct edema. These observations suggest that the success of cholangioscopy depends not only on device-related factors but also on patient selection and procedural conditions.

One of the most notable findings of our study was that cholangioscopy identified additional findings that altered clinical management in 20.4% of patients. Most of these findings were related to residual or difficult-to-localize bile duct stones that could not be detected using conventional techniques. In routine ERCP practice, procedural success is largely determined by fluoroscopic imaging and balloon occlusion cholangiography. However, residual stones may be overlooked, particularly in the presence of dilated bile ducts, significant pneumobilia, following stone fragmentation, or in situations where contrast material obscures small calculi.^{1,2} In the prospective tandem study by Sejpal et al., residual stones were detected in approximately one-quarter of patients despite negative balloon occlusion cholangiography.¹ Similarly, in the recent meta-analysis by Dall'Agnol et al., the overall rate of residual stone detection was reported as 27%, increasing to 32% in studies utilizing digital cholangioscopy systems.²

In our series, the rate of residual stone detection was 10.2%. Although this figure appears lower than those reported in the literature, it remains clinically relevant given the heterogeneity of the study population and the broad range of procedural indications. More importantly, cholangioscopy not only provided additional diagnostic information but also enabled immediate therapeutic intervention during the same session. Therefore, digital cholangioscopy may be considered a valuable adjunct for improving procedural completeness, particularly in patients at high risk for residual bile duct stones.

The clinical significance of residual stones extends beyond their being missed during the index procedure. These stones may subsequently lead to recurrent biliary pain, cholangitis, acute pancreatitis, and the need for repeat ERCP. Recurrence rates following ERCP have been reported to range from 4% to 24% in the literature.^{2,19} It has been suggested that a proportion of these "recurrent" stones may actually represent stones that were overlooked during the initial procedure. In our study, the low rate of repeat intervention for stone-related disease during long-term follow-up may indicate a beneficial effect of cholangioscopy-confirmed ductal clearance. However, prospective studies

comparing patients managed with and without cholangioscopy are needed to further clarify this association.

The applications of cholangioscopy continue to expand beyond stone disease. Indeterminate biliary strictures remain one of the major diagnostic challenges of conventional ERCP. Because the diagnostic sensitivity of standard brush cytology and fluoroscopy-guided biopsy is limited, additional diagnostic modalities are often required in patients with suspected malignancy.^{4,20,21} Current guidelines from the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG) recommend cholangioscopy-guided targeted biopsy sampling in selected patients when conventional tissue acquisition techniques are nondiagnostic.^{20,21} Similarly, the European Society of Gastrointestinal Endoscopy (ESGE) guideline emphasizes the role of cholangioscopy as an important adjunctive modality in the evaluation of indeterminate biliary strictures.⁴ In a meta-analysis by Wen et al., SpyGlass-guided targeted biopsy demonstrated high specificity for the diagnosis of biliary malignancy, whereas a systematic review by de Oliveira et al. reported high diagnostic accuracy of digital cholangioscopy for the visual assessment of indeterminate biliary strictures.^{5,22} Although the number of patients with intraductal lesions was limited in our series, the fact that cholangioscopy altered the diagnostic approach in two patients further supports its value in clinical decision-making.

One of the unique aspects of our study is the inclusion of intraoperative and perioperative cholangioscopy applications. Although the number of patients was limited, cholangioscopy was utilized in a variety of surgical scenarios, including the evaluation of complex biliary anatomy, identification of the source of bile leakage, and confirmation of ductal integrity following biliary reconstruction. Recent studies have demonstrated that digital cholangioscopy is not only feasible and safe in the endoscopy unit but can also be effectively integrated into hepatobiliary surgery. Fugazzola et al. reported high ductal clearance rates using the SpyGlass Discover system during laparoscopic transcystic bile duct exploration.¹⁴ Similarly, Abdelkader et al. demonstrated that simultaneous laparoscopic cholecystectomy and SpyGlass-assisted common bile duct exploration may represent an effective and cost-efficient strategy in selected patients.¹⁵ Taken together, these findings and our own experience suggest that cholangioscopy should be viewed not only as an advanced endoscopic tool but also as a potential component of multidisciplinary hepatobiliary practice.

From a safety perspective, the complication rates observed in our study were generally consistent with those reported in the contemporary literature. Post-ERCP pancreatitis occurred in 9.1% of patients, and all cases were mild in severity. As the most common complication of ERCP, post-ERCP pancreatitis has been reported in recent meta-analyses to occur in approximately 4%–10% of cases.^{23–25} Although the incidence observed in our cohort was near the upper limit of this range, the fact that all cases resolved with conservative management is reassuring. The relatively high proportion of patients with complex pancreatobiliary disorders may partially explain this finding. Furthermore, all patients received rectal indomethacin and intravenous hydration before the procedure, in accordance with current prophylactic strategies. The absence of perforation and bleeding requiring blood transfusion further supports the acceptable safety profile of the procedure.

Although the 30-day mortality rate was 1.8%, the patient who died had presented with severe acute pancreatitis and biliary sepsis at the time of admission. Death occurred following the development of necrotizing pancreatitis and multiple organ dysfunction syndrome after the procedure. Given the patient's advanced disease state and clinical condition at presentation, this event was not considered directly attributable to the procedure. Procedure-related mortality following ERCP is generally reported to range from 0.1% to

0.5% in the literature.²⁴ Therefore, this finding should be interpreted in the context of the patient's baseline clinical status rather than as a direct consequence of the intervention.

Only four patients required repeat intervention during a mean follow-up period of 30 months. A substantial proportion of these cases were related to complex benign strictures or pre-existing pancreatic stent-related problems. Excluding the patient who required surgical treatment for a migrated pancreatic stent, the rate of repeat intervention due to residual or recurrent stone disease remained very low. Considering the reported recurrence rates of 4%–24% in the literature, the low rate of repeat intervention observed in our series is noteworthy.^{2,19} Although the absence of a control group precludes any causal inference, our findings support the hypothesis that cholangioscopy-confirmed ductal clearance may contribute to reducing long-term biliary events.

Several limitations of this study should be acknowledged. First, its retrospective single-center design introduces the potential for selection bias. Although cholangioscopy was performed in all patients meeting the predefined clinical indications, the findings reflect the experience of a single institution and may therefore have limited generalizability. In addition, the absence of a control group precludes direct comparison with conventional ERCP. The sample size was also relatively small, particularly in the subgroups of patients with biliary strictures and those undergoing intraoperative cholangioscopy.

Despite these limitations, the study has several strengths. It reflects real-world clinical practice and includes a heterogeneous patient population encompassing a broad spectrum of indications beyond stone disease, including biliary strictures, migrated stents, and intraoperative applications. Furthermore, the availability of long-term follow-up data enabled assessment not only of procedural success but also of clinically relevant outcomes over time.

5. Conclusion

SpyGlass DS-assisted single-operator digital cholangioscopy performed concomitantly with ERCP is a valuable adjunct in the management of pancreatobiliary disorders, offering a high technical success rate, the ability to detect residual stones and intraductal lesions not identified by conventional techniques, therapeutic benefits in selected cases, and an acceptable safety profile. Direct intraductal visualization may provide important advantages, particularly in situations where conventional ERCP findings are inconclusive or when additional information is required to guide clinical decision-making. Furthermore, our findings suggest that digital cholangioscopy may serve not only as an advanced endoscopic tool but also as a useful adjunct in selected hepatobiliary surgical settings. Larger prospective comparative studies are warranted to validate these findings.

Statement of ethics: Ethical approval was obtained from the Human Research Ethics Committee of İstinye University İstanbul (decision no.: 2025-373, date: 10.04.2026) in compliance with the Declaration of Helsinki.

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Author Contributions: ÇB: Conceptualization, study design, data acquisition, drafting of the manuscript, final approval, and accountability for all aspects of the work. ES: Conceptualization, study design, data analysis and interpretation, drafting of the manuscript, final approval, and accountability for all aspects of the work. SB: Data acquisition, critical revision of the manuscript, final approval, and accountability for all aspects of the work. SEB: Study design, data analysis, critical revision of the manuscript, final approval, and accountability for all aspects of the work. BB: Conceptualization, supervision, drafting of the manuscript, final approval, and accountability for all aspects of the work.

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