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BILIARY TRACT (J BAILLIE, SECTION EDITOR)

The Usefulness of SpyGlass™ Choledochoscopy in the Diagnosis and Treatment of Biliary Disorders

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Abstract Peroral choledochoscopy was first described in the 1970s, but the use of earlier generation choledochoscopes was significantly limited by complex equipment setup and fragility resulting in high repair costs. In late 2006, the SpyGlass Direct Visualization System (Boston Scientific Corp, Natick, MA, USA) was introduced to the market. It is a single-operator cholangioscopy platform and improves upon many shortcomings of the dual-operator systems. Currently, the two main indications for its use are evaluation of indeterminate biliary strictures and lithotripsy for difficult-to-remove biliary stones. Recently published prospective data reconfirm that the overall success rates for adequate tissue sampling and bile duct stone clearance are around 90 %, with an acceptable safety profile. The sensitivity for detecting cancer in intrinsic biliary strictures (e.g., cholangiocarcinoma) is superior to that of standard ERCP sampling modalities, but a limited yield has been noted when sampling extrinsic malignant biliary strictures (e.g., pancreatic cancer). The two main limitations of the SpyGlass system are image quality that is impeded by the use of fiberoptic technology and a relatively small accessory channel providing passage only for dedicated miniaccessories. Nevertheless, the SpyGlass platform has made single-operator cholangioscopy feasible and refined the technique in a number of important ways. This innovation has significantly expanded our diagnostic and therapeutic ERCP armamentarium. An upgraded digital imaging version is currently in development.

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Introduction

Over the last 4 decades, evaluation and treatment of the bile ducts have been largely accomplished by endoscopic retrograde cholangiopancreatography (ERCP) [1]. Success rates for removal of common bile duct stones with ERCP-guided maneuvers are greater than 90 % [2, 3]. Nevertheless, some stones are difficult or impossible to extract with standard ERCP techniques. Furthermore, the sensitivity of ERCP-directed cytology brushings for diagnosis of a malignant biliary stricture has been disappointing, ranging from approximately 30 % to 40 % [4-6]. Several studies have evaluated a combined approach by incorporating endobiliary biopsy forceps and/or endoscopic needle aspiration with cytology brushings during ERCP, but diagnostic yield remains less than 70 %, with a low negative predictive value [7-9]. Endoscopic ultrasound (EUS) has been used more recently for evaluation of biliary strictures. Reported sensitivity for EUS-guided fine needle aspiration ranges from 43 % to 77 %, but negative predictive value is less than 30 % [10-12].

Another method of evaluating biliary duct pathology is intraductal endoscopy, otherwise known as cholangioscopy or choledochoscopy. The distinct advantage of cholangioscopy, as compared with ERCP, is the ability to obtain targeted biopsies or perform therapy under direct vision. Intraoperative choledochoscopy, initially intended to assess for residual stones after cholecystectomy, was described as early as 1941, and the first flexible fiberoptic choledochoscope was introduced in 1965 [13, 14]. The first reports of peroral choledochoscopy were published in the mid-1970s

[15-17]. Several studies since then have demonstrated that peroral choledochoscopy has a clear role in both diagnostic and therapeutic applications in the biliary tract [18-21]. Conventional cholangioscopy, though, had the disadvantages of being resource intensive and time consuming. Two endoscopists were needed to operate the "mother–baby" choledochoscopes, and many of the earlier models had a restrictive design. These conventional "baby" choledochoscopes had limited range of motion, lack of a dedicated irrigation channel, and fragility of the fiberoptic camera. The inherent fragility often generated significant downtime and high repair costs.

Shortly after introduction of the first peroral mother–baby choledochoscope, the first report of peroral direct cholangioscopy came in 1977 [22]. Most modern commercially available choledochoscopes still utilize the mother–baby design that requires two skilled endoscopists, but single-operator systems exist. "Ultra-slim" upper endoscopes, with an external diameter ranging from 5 to 6 mm, can be used for cholangioscopy. Because of this diameter, examination requires the presence of a dilated biliary duct and previous large biliary sphincterotomy. Insertion of the ultra-slim endoscope over a previously inserted guidewire is also usually required, and that can be technically challenging in many cases. The major advantages of these endoscopes, as compared with most mother–baby choledochoscopes, are the superior digital image quality and larger 2-mm working channel [23].

The SpyGlass Direct Visualization System (Boston Scientific Corp, Natick, MA, USA) was introduced in November 2006. At the present time, it is the only commercially available single-operator system for cholangiopancreatoscopy that utilizes a mother–baby configuration. It was designed to address many of the aforementioned shortcomings of existing cholangioscopy platforms. Due to the significant advantages of SpyGlass, the system has gained significant popularity, with over 800 practices using the platform and more than 35,000 procedures completed worldwide.

SpyGlass System and Compatible Equipment

The SpyGlass Direct Visualization System is an integrated product platform that combines capital components and disposable single- or multiple-use devices. It is also compatible with certain electrohydraulic lithotripsy (EHL) fibers and laser probes. Capital components consist of a video monitor and the SpyGlass travel cart housing the light source, camera, isolation transformer, and irrigation pump with footswitch. An extra space is provided on the cart for an EHL generator. Consumable devices include the disposable SpyScope access and delivery catheter, a reusable SpyGlass optical probe, and disposable SpyBite biopsy forceps (Table 1).

Table 1 Costs of SpyGlass equipment[a]

Capital components	Price	Disposable components	Price
Travel cart (with 3-joint arm)	$7,650	SpyScope catheter	$800
Light source	$10,975	SpyGlass ocular probe[b]	$4,400
Light cable	$1,475	SpyBite forceps	$575
Camera	$19,975		
Ocular piece	$3,675	EHL lithotripter[c]	$22,500
Irrigation pump (with footswitch)	$4,295		
Isolation transformer	$2,975		

[a] Approximate costs, which may vary based on contractual agreements

[b] SpyGlass ocular probe has a lifespan of approximately 20 uses

[c] Separate capital component, which is compatible with the SpyGlass platform

The SpyScope access and delivery catheter has a working length of 230 cm, an outer diameter of 10 F, and three separate ports: an optic port to accommodate the SpyGlass optical probe, an irrigation port that feeds into two dedicated 0.6-mm irrigation channels, and a 1.2-mm accessory channel that can accommodate the SpyBite biopsy forceps, EHL fibers, or a holmium laser probe. The SpyBite biopsy forceps has a working length of 286 cm, a jaw opening diameter of 4.1 mm, and a central spike to aid in securing small tissue samples. For EHL, the Northgate Autolith iEHL Generator with the 1.9 F Biliary Probe (Northgate Technologies Inc., Elgin, IL, USA) can be used. Typical initial settings for the EHL generator are 10 pulses per second and power output of 40 %. The power output can be titrated up as needed to the maximum output of 100 %. For laser lithotripsy, the VersaPulse PowerSuite 20 Watt Holmium laser (at a constant setting of 0.8 Joules and 8 pulses per second) with the SlimLine 365-μm Blue Jacket fiber (Lumenis Inc., Santa Clara, CA, USA) can be used. The SpyGlass optical probe is a 6,000-pixel fiberoptic bundle that has a 70° field of view. It can be reprocessed after each use via high-level disinfection, which has been demonstrated in ex vivo experiments to be efficacious and result in no demonstrable deterioration in image quality after 20 uses [24]. For comparative purposes, the SpyGlass optical probe has an optical resolution approximately twice that of the Olympus CHF BP30 choledochoscope (Olympus America Inc., Center Valley, PA, USA) [24]. Although there has been no formal comparison, the image quality of the SpyGlass optical probe remains inferior to currently available choledochoscopes that utilize video imaging [23]. Furthermore, the fiberoptic probe remains susceptible to partial breakage during use, which can result in image degradation.

Additional improvements with the SpyGlass platform, as compared with conventional cholangioscope systems, include four-way tip deflection of the SpyScope, improved irrigation

capabilities, single-operator use, and smaller diameter (10 F). In a laboratory simulation, four-way deflected steering increased successful biopsy target access and simulated biopsy by 2.09 and 2.94 times, respectively, as compared with a control system that utilized only two-way steering [24]. In the same study, irrigation flow rates with a biopsy forceps loaded in the working channel were significantly higher in the SpyGlass system, as compared with two control choledochoscopes (CHF BP30, Olympus; and FCP-9P, Pentax Medical Co., Montvale, NJ, USA). The advantage of a single-operator system is self-evident as a time-saving benefit, and the smaller diameter can theoretically allow greater access in the biliary system.

The SpyGlass components can be introduced through a duodenoscope or colonoscope that has a minimum working channel diameter of 3.4 mm [23, 25-27, 28••]. The SpyScope catheter is strapped to the duodenoscope or colonoscope by a silastic belt just below the operating channel, so that a single operator can control both systems (see Fig. 1).

Feasibility of SpyGlass Use

Earlier cholangioscopy platforms were plagued by the need for expensive and fragile equipment that required complex setup and also needed two skilled endoscopists. The SpyGlass Direct Visualization System appeared to have successfully addressed the majority of these problems. Therefore, in our center, we prospectively evaluated the feasibility of using the SpyGlass system in everyday practice [28••]. For the 83 procedures included in our series, the mean total procedure time (standard ERCP plus SpyGlass) was 64.3 min (±25.1), the total SpyGlass time was 27.5 min (±16.7), and the mean SpyGlass visualization time was 14.2 min (±10.9). SpyBite sampling was attempted in 37 procedures with a mean sampling time of 12.1 min (±6.34). SpyGlass-directed therapy was performed in 28 procedures with a mean therapy time of 8.4 min (±14.57). In 20 procedures, setup of the SpyGlass equipment (after ERCP had started) took a mean of 5 min (±2.39). These data confirm that SpyGlass choledochoscopy is clinically feasible in a busy endoscopy unit.

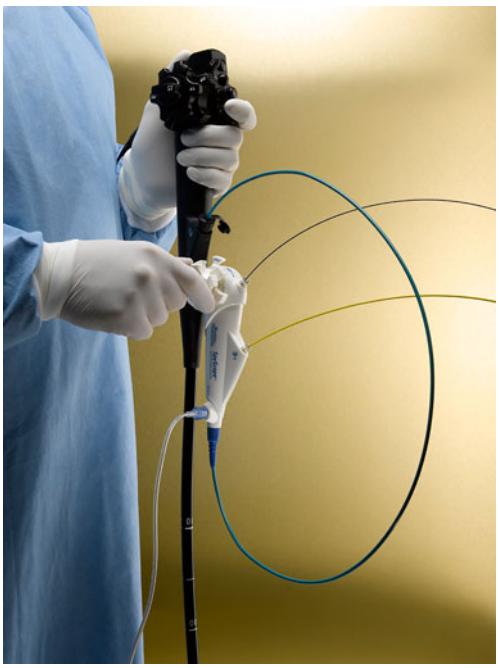

Fig. 1 SpyScope attached to duodenoscope

Diagnostic Indications

Direct visualization and biopsy of indeterminate biliary lesions is one of the main indications for SpyGlass choledochoscopy [27, 28••, 29•] (Table 2). Accurate diagnosis of biliary strictures or filling defects is essential for appropriate treatment planning. Certain visual indicators, such as intraductal masses or dilated and tortuous vessels (so-called tumor vessels), have been described in the literature to be highly specific for malignant bile duct lesions [30]. The presence of such findings can suggest malignancy, but definitive diagnosis requires histological assessment. There was initial skepticism regarding the SpyBite forceps' limited opening diameter, which could limit adequate tissue acquisition. However, studies have shown that the sampling yield of SpyBite forceps in obtaining tissue that is adequate for pathologic evaluation ranges from 82 % to 97 % [27, 28••, 29•, 31••, 32••]. A prospective paired design study at our institution used triple sampling during ERCP to compare SpyBite miniforceps biopsies with standard cytology brushings and standard forceps biopsies [32••]. On pathologic evaluation, sample quality was considered adequate in 25 of 26 of the cytology brushings (96 %), in 26 of 26 of the standard forceps biopsies (100 %), and in 25 of 26 of the SpyBite miniforceps biopsies (96 %).

Table 2 Indications for SpyGlass choledochoscopy

Diagnostic indications	Therapeutic indications
Indeterminate biliary stricture	Lithotripsy for choledocholithiasis
Indeterminate biliary filling defect	Treatment of a biliary stricture
Staging of cholangiocarcinoma	Transpapillary gallbladder drainage
Biliary cyst evaluation	Foreign body removal (e.g., stent)
Bile duct ischemia evaluation (post-liver-transplant)	Biliary guidewire placement
Hemobilia	
Ampullary adenoma (assess for ductal involvement)	
Verification of bile duct stone clearance	

Importantly, SpyGlass-directed sampling not only provides biopsy specimens that are adequate for evaluation, but ultimately can secure accurate tissue diagnosis. On the basis of data from three high-quality prospective trials, the diagnostic accuracy of SpyBite forceps biopsy for indeterminate biliary lesions ranges from 72 % to 85 %, with a sensitivity of 49 % to 82 %, a specificity of 82 % to 100 %, a positive predictive value of 100 %, and a negative predictive value of 69 % to 100 % [29•, 31••, 32••]. The lower specificity in one trial (82 %) was driven by biopsy results that were inadequate for histological interpretation in an intention-to-treat analysis [29•]. For the most part, though, both specificity and positive predictive value of SpyBite sampling approach 100 %. This is neither unexpected nor different from traditional methods of tissue sampling, such as cytology brushings and standard forceps biopsy [8-10]. On the other hand, the common limitation among traditional sampling methods (cytology brushings and fluoroscopically guided biopsies) has been the low sensitivity and negative predictive value, both of which are due to the relative high rate of false-negative results. Cholangioscopic visualization can potentially circumvent this deficiency by allowing mucosal assessment and targeted biopsies obtained under direct vision. Direct comparison of SpyBite forceps biopsy with cytology brushings and standard forceps biopsy in a prospective, long-term follow-up study showed a significant increase in sensitivity (76.5 % vs. 5.8 % and 29.4 %, respectively) and higher negative predictive value (69.2 % vs. 36 % and 42.8 %, respectively) [32••]. The sensitivity of cytology brushings (5.8 %) in this study was unusually low, possibly due to the fact that 69 % of the lesions were located in the hilar region or proximal bile duct. Another possible explanation is the strict definition for malignancy used in this trial, as specimens interpreted as atypical or suspicious were considered benign for the purpose of the analysis. Nevertheless, using the same definition, the sensitivity for SpyBite forceps biopsy was significantly higher at 76.5 %. Importantly, a majority of bile duct lesions included in this trial were intrinsic (e.g., cholangiocarcinoma).

The sensitivity of SpyGlass visualization alone was also assessed in two of the prospective trials and was found to be even higher (84 %–95 %) than SpyBite biopsy (49 %–82 %) [29•, 31••]. The higher sensitivity for visualization alone may be explained by the ability to detect not only epithelial lesions, but also tumors causing extrinsic compression of the biliary system. However, neither SpyBite miniforceps nor standard forceps can target extrinsic lesions unless the tumor has penetrated the biliary mucosa. Results from one of the prospective trials suggested this fact, since the sensitivity of SpyBite forceps biopsy was far higher for intrinsic (66 %) than for extrinsic (8 %) malignant lesions [31••]. By contrast, the sensitivity of SpyGlass visual impression alone was less severely compromised for extrinsic (62 %) than for intrinsic (84 %) lesions [31••].

Unfortunately, specificity is compromised by utilizing direct visualization alone. Not only may extrinsic compression be due to a benign etiology, but also certain intraductal diseases, such as primary sclerosing cholangitis, can have irregular biliary mucosa without harboring malignancy [27]. This can lead to false-positive results when cholangioscopic visualization is used as a sole modality for diagnosis. Further studies are needed to determine whether sampling techniques, such as an increased number of SpyBite forceps passes, can enhance SpyBite biopsy sensitivity.

Endoscopic ultrasound with fine needle aspiration (EUS-FNA) has been shown to be of value in securing the tissue diagnosis in patients with malignant biliary strictures that had prior nondiagnostic standard ERCP-based sampling [10-12]. A recently published retrospective case series reported on the diagnostic yield of SpyGlass sampling in patients with cholangiocarcinoma that had prior negative ERCP-based brush cytology and negative EUS-FNA [33]. Cholangioscopy with targeted SpyBite biopsy provided for positive tissue diagnosis in 77 % of the cases. Importantly, for the purpose of this study, samples interpreted as both positive for cancer and highly suspicious for cancer were considered diagnostic for malignancy.

In summary, SpyGlass choledochoscopy significantly facilitates the diagnosis of intrinsic malignant biliary strictures (cholangiocarcinoma) by providing a means for direct visualization of the lesion and by securing a tissue diagnosis in patients with prior negative sampling. The yield in patients with bile duct strictures due to extrinsic malignancy (pancreatic cancer) appears to be lower.

Less common diagnostic indications for SpyGlass choledochoscopy include evaluation of cystic lesions in the biliary tract, staging of cholangiocarcinoma, verification of bile duct stone clearance, evaluation for bile duct ischemia after liver transplantation, investigation of hemobilia, and evaluation for bile duct involvement in the presence of an ampullary adenoma [27, 28••, 29•, 34•, 35] (Table 2). Successful use of the SpyGlass system has also been reported in patients with postsurgical Roux-en-Y and post-Billroth II gastrectomy anatomy [26, 35, 36].

Therapeutic Indications

The major therapeutic application for the SpyGlass system is lithotripsy for biliary stones that remain after conventional ERCP methods have failed (Table 2). In most cases, bile duct stones can be successfully extracted after sphincterotomy with the use of extraction balloons or retrieval baskets

[3]. For difficult-to-remove stones, mechanical lithotripsy has been the traditional approach [3]. Biliary stones may be difficult to remove due to one or more factors, including stone size, stone location (e.g., intrahepatic biliary ducts), stone with a hard consistency, impacted stones, stone shape (e.g., piston shaped), size of the bile duct, shape of the bile duct (e.g., sigmoid shaped), low take-off of the cystic duct, and the presence of a periampullary diverticulum [3, 37, 38]. Furthermore, although ERCP is considered the gold standard for documenting choledocholithiasis, it is far from perfect. Standard fluoroscopy-based cholangiograms routinely miss stones or stone fragments remaining after lithotripsy. In recently published studies, previous ERCP failed to correctly identify choledocholithiasis in 8 %–16 % of cases referred for SpyGlass choledochoscopy [27, 29•, 34•]. SpyGlass choledochoscopy has been shown to be beneficial for the initial diagnosis of bile duct stones, for documentation of residual stone burden after what was believed to be complete bile duct clearance, and most important, for therapy of difficult-to-remove biliary stones.

A high success rate for SpyGlass-guided lithotripsy, ranging from 90 % to 100 %, has been documented in a number of series [27, 28••, 31••, 34•, 39]. Importantly, complete stone clearance was achieved in only one session in the vast majority of cases. Furthermore, SpyGlass choledochoscopy obviated the cumbersome use of mechanical lithotripsy [27, 28••]. EHL is used in most cases, but use of a holmium laser for lithotripsy has also been described [34•, 39]. Another distinct advantage of the SpyGlass platform, as opposed to conventional choledochoscopes, is the dedicated irrigation channels that allow a strong flow of water to continuously fill the biliary system with fluid, which is a requirement for effective EHL.

Other reported therapeutic applications of the SpyGlass system include treatment of a post-liver-transplant anastomotic biliary stricture, transpapillary gallbladder drainage in acute cholecystitis, removal of a bile duct foreign body, and assistance in guidewire placement [3, 40-42] (Table 2). SpyGlass-guided EHL via a therapeutic colonoscope has also been successfully used in a patient with choledocholithiasis and Roux-en-Y anatomy [25]. Another pertinent therapeutic application of SpyGlass that has been reported is to manage choledocholithiasis during a first-trimester pregnancy [43]. This technique allows for limitation or elimination of radiation exposure during stone removal, making it an attractive tool for therapy in pregnant or young patients.

Miscellaneous Uses of the SpyGlass System and its Components

Not only can the SpyGlass system be used to evaluate the biliary system, but also it has been used to evaluate main pancreatic duct pathology and for therapeutic maneuvers in the pancreatic duct. Success rates for pancreatoscopy (50 %–60 %) have been lower than for cholangioscopy, likely due to the smaller caliber of the pancreatic duct [28••, 34•]. Successful evaluation for intraductal papillary mucinous neoplasm (IPMN) and therapy for pancreatic duct stones have been described [28••, 34•]. Retrieval of pancreatic stents that had migrated "upstream" and were not amenable to removal by ERCP alone has also been described [44, 45].

Several reports in the literature have described the "off-label" utilization of SpyGlass, or specific parts of the system, to aid in diagnostic or therapeutic applications outside the biliary tract. Use of the SpyGlass optical probe has been used with a prototype forward-viewing echoendoscope for assistance in therapy of a completely obstructed colonic anastomosis. In this instance, the 0.9-mm SpyGlass optical probe was used to confirm the position in the proximal colon after recanalization and before wire-guided balloon dilation of the anastomosis [46]. Another case report describes use of the SpyGlass system to visualize and biopsy an 8-cm pancreatic cystic lesion that was incompletely characterized by EUS. A small cyst-gastrostomy opening was created prior to introduction of the SpyScope catheter, and the intent was to evaluate and biopsy an ill-defined hyperechoic region seen on EUS near the cyst wall [47]. No complications were reported with either of these procedures.

Safety

Reported adverse events during use of the SpyGlass system are comparable to those reported for ERCP [2, 48-50]. In a multicenter, prospective cohort study involving 297 patients, the incidence of procedure-related adverse events was 7.5 % for diagnostic SpyGlass use and 6.1 % for SpyGlass-directed stone therapy [36]. The most frequent adverse event in this study was early cholangitis (3.1 %), but no deaths attributable to cholangioscopy were reported. Other adverse events associated with diagnostic cholangioscopy included bacteremia (0.9 %), transient hypotension (0.9 %), abdominal pain/distention (0.9 %), pancreatitis (0.4 %), elevation in amylase and lipase without clinical pancreatitis (0.4 %), ERCP-related nausea with vomiting and abdominal pain (0.4 %), and radiculopathy (0.4 %). For the therapeutic group, additional adverse events included bile duct perforation in 1 patient (1.5 %) and both ERCP-related duodenal perforation and cholangioscopy-related transient desaturation secondary to aspiration in another (1.5 %).

Incidence of adverse events reported from two additional prospective trials are similar [28••, 29•]. In one trial that utilized diagnostic SpyGlass choledochoscopy to evaluate 36 patients who had indeterminate biliary strictures and/or filling defects, cholangitis that resolved with antibiotic

therapy occurred in 2 patients (5.6 %), and mild pancreatitis developed in 1 (2.8 %), during a follow-up of at least 1 month [29•]. The other trial enrolled patients for diagnostic (58.7 %) and therapeutic (34.7 %) cholangioscopy, as well as pancreatoscopy (6.7 %), and the adverse event rate in this study was 4.8 % [28••]. Three patients had mild post-ERCP pancreatitis, and 1 patient had a periampullary perforation caused by a biliary sphincterotomy. This patient recovered with conservative management that included antibiotics and nasogastric tube suction.

Another study retrospectively reviewed adverse events for 3,475 ERCP-only procedures (excluding sphincter of Oddi manometry cases) and 402 ERCPs with cholangiopancreatoscopy, only some of which utilized the SpyGlass platform [51•]. The authors found a significantly higher rate of adverse events with combined ERCP and cholangiopancreatoscopy, as compared with the ERCP-only group (7 % vs. 2.9 %). There was a similar rate of pancreatitis and perforation among the groups, but a significantly higher rate of cholangitis in the group that underwent combined ERCP with cholangiopancreatoscopy (1 % vs. 0.2 %). A proposed reason for the higher rate of cholangitis in the cholangiopancreatoscopy group is the use of intermittent saline solution irrigation during cholangiopancreatoscopy to obtain adequate visualization and to perform intraductal lithotripsy when necessary [51•]. It is important to note that the rate of adverse events for the ERCP-only group in this study is lower than what has been reported in the literature for ERCP.

Financial Considerations

Costs for the SpyGlass Direct Visualization System can be broken down into capital cost and the cost of each disposable component (Table 1). The combined list price for all capital components is approximately $55,000, although negotiated prices can be lower for some hospitals on the basis of contractual agreements. Overall capital cost for Spyglass is comparable to that for other cholangioscopy platforms [52]. The SpyGlass optical probe, which is reusable, is priced at $4,400. The SpyScope catheter and SpyBite forceps, both disposable components, currently cost $800 and $575, respectively.

There is a Current Procedural Terminology (CPT) code for peroral cholangioscopy only as an add-on (43273) that must be reported with at least one ERCP code. Medicare physician reimbursement for the add-on portion is $129, and hospital outpatient payment is $864.

Conclusion

The SpyGlass Direct Visualization System has significantly expanded our diagnostic and therapeutic capabilities. The two main indications for its use are the evaluation of indeterminate biliary strictures and therapy for choledocholithiasis after conventional ERCP methods have failed. High-quality prospective data show that a high rate of success can be achieved for both diagnostic and therapeutic procedures. The SpyGlass platform has made cholangioscopy feasible in everyday practice and has distinct advantages that have translated into improved outcomes.

Disclosure No potential conflicts of interest relevant to this article were reported.

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