

Topic	Authors, Periodical	Points to consider
<p>Strictures:</p> <p>SpyBite vs. Brushing</p>	<p>Digital single-operator peroral cholangioscopy-guided biopsy sampling versus ERCP-guided brushing for indeterminate biliary strictures: a prospective, randomized, multicenter trial (with video)</p> <p>Gerges C1, Beyna T1, Tang RSY2, Bahin F1, Lau JYW2, van Geenen E3, Neuhaus H1, Nageshwar Reddy D4, Ramchandani M5.</p> <p>Multiple Centers Gastrointest Endosc. 2019 Nov 25. pii: S0016-5107(19)32475-7. doi: 10.1016/j.gie.2019.11.025.</p>	<ul style="list-style-type: none"> • Patients with an indeterminate biliary stricture on the basis of MRCP were randomized to standard ERCP visualization with tissue brushing (control arm [CA]) or DSOC visualization and DSOC-guided biopsy sampling (study arm [SA]). This was a prospective, international, multicenter trial with a procedure-blinded pathologist. • Sensitivity of DSOC-guided biopsy samples was significantly higher than ERCP-guided brushing (SA 68.2% vs CA 21.4%, P < .01). The sensitivity of visualization (SA 95.5% vs CA 66.7%, P = .02) and overall accuracy (SA 87.1% vs CA 65.5%, P = .05) were significantly higher in the SA compared with the CA, whereas specificity, positive predictive value, and negative predictive value showed no significant difference. Adverse events were equally low in both arms. • DSOC-guided biopsy sampling was shown to be safe and effective with a higher sensitivity compared with standard ERCP techniques in the visual and histopathologic diagnosis of indeterminate biliary strictures. (Clinical trial registration number: NCT03140007.) • The Monaco classification identifies 8 visual criteria for biliary lesions on single-operator digital cholangioscopy. Using the criteria, the IOA and diagnostic accuracy rate of DSOC is improved compared with prior studies
<p>Strictures:</p> <p>SpyBite Tissue Processing</p>	<p>Optimizing Outcomes of Single-Operator Cholangioscopy-Guided Biopsies Based on a Randomized Trial</p> <p>Bang JY, Navaneethan, Hasan, Sutton, Hawes, Varadarajulu.</p> <p>CIE AdventHealth Clin Gastroenterol Hepatol. 2020 Feb;18(2):441-448.e1. doi: 10.1016/j.cgh.2019.07.035. Epub 2019 Jul 24.</p>	<p>Purpose - The primary outcome was to compare operating characteristics of onsite vs offsite specimen processing techniques. The secondary outcome was number of biopsies needed to establish definitive diagnosis.</p> <ul style="list-style-type: none"> • No significant differences between the offsite and onsite groups in diagnostic accuracy (90% vs 87.5%; P=.99), sensitivity (76.9% vs 75%; P=.99), specificity (100% vs 100%; P=.99), positive predictive value (100% vs 100%; P=.99), or negative predictive value (85% vs 80%; P=.99). • Although diagnoses were established by analysis of a median of 1 biopsy in the onsite cohort (interquartile range, 1-1.5), the diagnostic accuracy was identical (90%) in each group, regardless of whether 3 or 4 biopsies were collected from each patient in the offsite cohort • Centers without onsite cytopathology support that analyze 3 single-operator cholangioscopy-guided biopsies of a biliary stricture and process the specimens offsite make the correct diagnosis for 90% of cases. ClinicalTrials.gov, Number: NCT01815619.
<p>Strictures:</p> <p>Visual Diagnostics</p>	<p>Digital Single-operator Cholangioscopy (DSOC) Improves Interobserver Agreement (IOA) and Accuracy for Evaluation of Indeterminate Biliary Strictures: The Monaco Classification.</p> <p>Sethi A1, Tyberg A2, Slivka A3, Adler DG4, Desai AP1, Sejpal DV5, Pleskow DK6, Bertani H7, Gan SI8, Shah R9, Arnelo U10, Tarnasky PR11, Banerjee S12, Itoi T13, Moon JH14, Kim DC14, Gaidhane M2, Raijman I15, Peterson BT16, Gress FG17, Kahaleh M2.</p> <p>Multiple Centers J Clin Gastroenterol. 2020 Feb 7. doi: 10.1097/MCG.0000000000001321</p>	<p>Purpose - Visual characteristics seen during digital single-operator cholangioscopy (DSOC) have not been validated. The aim of this 2-phase study was to define terminology by consensus for the visual diagnosis of biliary lesions to develop a model for optimization of the diagnostic performance of DSOC.</p> <ul style="list-style-type: none"> • Phase 1 - Criteria Identification - Video-cholangioscopy clips were reviewed by 12 expert biliary endoscopists, who were blinded to the final diagnosis. Visual criteria were consolidated into the following categories: (1) stricture, (2) lesion, (3) mucosal features, (4) papillary projections, (5) ulceration, (6) abnormal vessels, (7) scarring, (8) pronounced pit pattern. • Phase 2 - Validation - 14 expert endoscopists reviewed DSOC (SpyGlass DS, Boston Scientific) clips using the 8 criteria above to assess interobserver agreement (IOA) rate • Phase 1 Results - Consensus for visual findings were categorized into 8 criteria titled the "Monaco Classification." The frequency of criteria were: (1) presence of stricture-75%, (2) presence of lesion type-55%, (3) mucosal features-55%, (4) papillary projections-45%, (5) ulceration-42.5%, (6) abnormal vessels-10%, (7) scarring-40%, and (8) pronounced pit pattern-10%. The accuracy on final diagnosis based on visual impression alone was 70%. • Phase 2 Results - The IOA rate using Monaco Classification criteria ranged from slight to fair. The presumptive diagnosis IOA was fair ($\kappa=0.31$, $SE=0.02$), and overall diagnostic accuracy was 70%.

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<p>Selective Guidewire Placement</p> <p>SpyBite vs. Brushing</p>	<p>Digital single-operator cholangioscopy: a useful tool for selective guidewire placements across complex biliary strictures</p> <p>Bokemeyer A1, Gross D1, Brückner M1, Nowacki T1, Bettenworth D1, Schmidt H1, Heinzow H1, Kabar I1, Ullerich H1, Lenze F2.</p>	<p>Purpose - Treatment of biliary strictures is challenging. Digital single-operator cholangioscopes (SOCs) equipped with an improved imaging quality, were recently introduced and may be useful for selective guidewire placement in difficult biliary strictures.</p> <ul style="list-style-type: none"> • A total of 167 digital SOC procedures performed between 2015 and 2018 were retrospectively analyzed for successful guidewire placements across biliary strictures. Only cases with previous failed conventional guidewire placement approaches were included • 30 examinations with a digital SOC-assisted guidewire placement across biliary strictures, performed in 23 patients, were identified. <ul style="list-style-type: none"> o 52% of all patients, the stricture was benign with post-liver-transplant strictures as the most frequent finding (75%) o 48% of all patients the stricture was malignant with cholangiocellular carcinoma as the most frequent type (64%). o Guidewire placement was successful in 21 of 30 procedures (70%). o SOC-assisted guidewire placements were significantly more successful in patients with benign strictures than those in patients with malignant strictures (88.2% vs. 46.2%; p = 0.02). o Technical success rate increased in cases of initial examinations (78.3%) than in patients with repeated examinations (42.9%; p = 0.15) • Digital SOC-assisted guidewire placements have high technical success rates, especially in benign biliary strictures. This technique can help to avoid more invasive procedures such as percutaneous transhepatic or endoscopic ultrasound-guided biliary drainage.
<p>Stone Mgmt:</p> <p>SpyDS/EHL for Difficult Stone</p>	<p>Digital single-operator video cholangioscopy in treating refractory biliary stones: a multicenter observational study.</p> <p>Bokemeyer A1, Gerges C2, Lang D2, Bettenworth D1, Kabar I1, Schmidt H1, Neuhaus H2, Ullerich H1, Lenze F1, Beyna T3.</p> <p>Multiple Centers Surg Endosc. 2019 Jul 15. doi: 10.1007/s00464-019-06962-0. [Epub ahead of print]</p>	<p>Purpose - investigate the efficacy and safety of recently introduced digital single-operator video cholangioscopy (SOVC) for the treatment of difficult biliary stones and evaluate the stone removal rate per procedure and per patient</p> <ul style="list-style-type: none"> • 75 examinations with a digital SOVC-assisted biliary stone treatment, performed in 60 patients, were identified. Biliary stones were mainly located extrahepatic (64%) and less frequently intrahepatic (36%). The median stone size was 20 mm and the median stone number was 1. • Digital SOVC-based treatment of biliary stone disease was successful in 95% of patients and 15% needed at least two treatment sessions. • complete stone removal was accomplished in 67% of all examinations (including initial and repeated procedures), while an incomplete stone removal was observed in 33% of cases. • Digital SOVC-assisted biliary stone treatment is highly effective even in cases with difficult biliary stones and might be considered the new standard of care for these patients.

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<p>Stone Mgmt: AMEA Registry – BSC Sponsored</p>	<p>Cholangioscopy-guided lithotripsy for difficult bile duct stone clearance in a single session of ERCP: results from a large multinational registry demonstrate high success rates.</p> <p>Maydeo AP1, Rerknimitr R2, Lau JY3, Aljebreen A4, Niaz SK5, Itoi T6, Ang TL7, Reichenberger J8, Seo DW9, Ramchandani MK10, Devereaux BM11, Lee JK12, Goenka MK13, Sud R14, Nguyen NQ15, Kochhar R16, Peetermans J17, Goswamy PG17, Rousseau M17, Bhandari SP1, Angsuwatcharakon P2, Tang RSY3, Teoh AYB3, Almadi M4, Lee YN18, Moon JH18; SpyGlass AMEA Registry Group.</p> <p>Multiple Centers Endoscopy. 2019 Oct;51(10):922-929. Doi: 10.1055/a-0942-9336. Epub 2019 Jun 27.</p>	<p>Purpose - provide prospective multinational data on PSOC-guided lithotripsy for clearing difficult bile duct stones in a single session of endoscopic retrograde cholangiopancreatography (ERCP).</p> <ul style="list-style-type: none"> • Patients with difficult bile duct stones (defined as one or more of: largest stone diameter ≥ 15 mm, failed prior attempt at stone clearance, impacted, multiple, hepatic duct location, or located above a stricture) were enrolled at 17 centers in 10 countries. The principal endpoint was stone clearance in a single ERCP procedure using PSOC. • 156 patients underwent 174 sessions of PSOC-guided electrohydraulic or laser lithotripsy. Stone clearance had failed in a previous ERCP using traditional techniques in 124/156 patients (80%), while 32/156 patients (21%) were referred directly to PSOC-guided therapy based on preprocedural assessment of the difficulty of stone clearance. In 101/156 patients (65%), there were impacted stones. • PSOC-guided stone clearance was achieved in a single PSOC procedure in 125 /156 patients (80 %, 95 % confidence interval [CI] 73%-86%), and was significantly more likely for stones ≤30mm compared with >30mm (odds ratio 7.9, 95%CI 2.4-26.2; P=0.002) • PSOC-guided lithotripsy is highly effective for clearance of difficult bile duct stones in a single procedure and successfully salvages most prior treatment failures. It may also be considered first-line therapy for patients with difficult choledocholithiasis to avoid serial procedures
<p>Stone Mgmt: Radiation Free Cholangioscopy</p>	<p>A prospective evaluation of radiation-free direct solitary cholangioscopy for the management of choledocholithiasis</p> <p>Barakat, Girotra, Choudhary, Huang, Sethi, Banerjee Gastrointestinal Endoscopy. Aug 7, 2017.</p>	<p>Purpose - ERCP remains a hybrid endoscopic-fluoroscopic procedure, which limits portable delivery, creates delays because of fluoroscopy room availability and exposes patients and providers to radiation. This aim of this study is to evaluate the safety of radiation free cholangioscopy.in patients with noncomplex choledocholithiasis.</p> <ul style="list-style-type: none"> • Fluoro free cannulation was successful in all 40 patients and extraction was successful in all 39 patients where stone/debris/sludge was found. • Brief fluoro was used in 2 patients (5%) to confirm stone clearance. • Mild pancreatitis was noted in 2 patients (5%) and bleeding in 1 (2.5%) • This study establishes the feasibility of fluoroscopy/radiation-free cholangioscopic management of noncomplex choledocholithiasis. Cholangioscopy does not need to be confined to the fluoroscopy suite and can be reimaged as a bedside procedure in the emergency department or intensive care settings.
<p>Stone Mgmt: Lithotripsy Device Comparison</p>	<p>Biliary and Pancreatic Lithotripsy Devices</p> <p>Watson, Parsi, Aslanian, et al. Gastrointestinal Endoscopy. Sep 26 2018</p>	<p>Purpose - Review devices and methods for biliary and pancreatic lithotripsy and the evidence regarding efficacy, safety and financial considerations</p> <ul style="list-style-type: none"> • EHL and Laser lithotripsy are effective at ductal clearance when conventional techniques are unsuccessful, although they require direct visualization of the stone. • Extracorporeal shockwave lithotripsy is effective but often requires coordination with urologists and the placement of stents or drains, as well as additional procedures for extracting fragments which may be associated with increased costs.

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<p>Strictures:</p> <p>Comparison of Methods for Diagnosing Biliary Strictures</p>	<p>Comparative Effectiveness of Various ERCP Based Modalities for Detection of Malignant Biliary Strictures</p> <p>Navaneethan, Zhu, Lourdusamy, Lourdusamy, Varadarajulu</p> <p>GIE. AB216. Sa1378. Volume 85. No 5S 2017.</p>	<p>Purpose: Evaluate clinical effectiveness of multiple ERCP based modalities for diagnosing biliary strictures</p> <ul style="list-style-type: none"> Retrospective analysis of 31 studies. A bivariate model was used to compute pooled sensitivity and specificity for all modalities studied (15 on brushing, 6 intraductal biopsy, 4 Confocal Laser Endomicroscopy (CLE), 5 Single Operator Cholangioscopy (SOC) and 1 Digital SOC. Sensitivity was 56% for Cytology, 61% for Biopsy, 81% for SOC, 85% for DSOC and 94% for CLE Diagnostic Accuracy was 70% for Cytology and Biopsy, 86% for SOC, 93% for DSOC and 81% for CLE
<p>Stricture + Stone:</p> <p>Effectiveness of Digital SOC for Stricture and Stones</p>	<p>Digital Single Operator Cholangiopancreatography in the diagnosis and management of pancreaticobiliary disorders: a multicenter clinical experience</p> <p>Navaneethan, Hasan, Kommaraju et al.</p> <p>GIE. 2016. Vol 84 No 4. 649-55</p>	<p>Purpose - Review performance of a new digital, single operator cholangioscope (DSOC)</p> <ul style="list-style-type: none"> Multicenter (2), observational study of 105 consecutive patients with suspected pancreaticobiliary disorders (98 cholangioscopy and 7 pancreatoscopy procedures) 44 patients underwent SOC-guided biopsies, tissue was adequate for histologic evaluation in 97% of patients. Sensitivity and specificity of visual impression was 90% and 95% respectively. Sensitivity and specificity of biopsies was 85% and 100% respectively In patients with pancreatic or biliary duct stones (N=36), complete duct clearance was achieved in 1 session in 86% of patients. Three patients experienced SOC related adverse events (2 cholangitis and 1 post-ERCP pancreatitis).
<p>Stone Mgmt:</p> <p>Difficult Biliary Stones</p>	<p>Efficacy and Safety of Digital Single-Operator Cholangioscopy for Difficult Biliary Stones</p> <p>Gutierrez, Bekkali, Raijman, et al</p> <p>Clinical Gastroenterology and Hepatology. Oct 23, 2017</p>	<p>Purpose - Evaluate the effectiveness and safety of digital single operator cholangioscopy (DSOC) with electrohydraulic (EHL) and laser lithotripsy (LL) to treat difficult biliary stones</p> <ul style="list-style-type: none"> Retrospective analysis of 407 patients with difficult biliary stones treated at 22 tertiary centers in the U.S., UK and Korea. 306 underwent EHL and 101 underwent LL. Mean treatment time was longer for EHL cohort (74 minutes) than LL cohort (50 minutes). Ductal clearance was achieved in 97% of patients (96.7% for EHL, 99% for LL) Single session clearance achieved in 77% of patients (74.5% for EHL and 86.1% for LL) EHL or LL failed in 8 patients (2.7%), who were subsequently referred for surgery to treat the stones. Adverse events occurred in 3.7% of patients and stone was incompletely removed in 6.6% of patients. These were rated as mild (n = 10; 66.7%), moderate (n = 3; 20%), and severe (n = 2; 13.3%), as per American Society for Gastrointestinal Endoscopy lexicon. Conclusion: in this multicenter, international, retrospective analysis, D-SOC with EHL or LL was found to be effective and safe in more than 95% of patients with difficult biliary stones. Fewer than 5% of patients required additional treatment (e.g., surgery and/or extra-corporeal shockwave therapy)

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<p>Stricture + First in-human evaluation of Spy DS</p>	<p>Performance of a fully disposable, digital, single-operator cholangiopancreatroscope</p> <p>Shah, Raijman, Brauer, Gumustop, Pleskow</p> <p>Endoscopy 2017. 49:651-658</p>	<p>Purpose: Evaluate first in human use of the SpyGlass DS digital single operator cholangioscopy system for diagnosis of indeterminate strictures and treatment of difficult stones</p> <ul style="list-style-type: none"> • This was a four center, retrospective analysis of data from 108 patients between February 2015 – April 2015. • Of 74 patients with indeterminate strictures, 29 (39%) had neoplasia. Operating characteristics for SpyGlass visual impression were 97% sensitivity, 93% specificity, 90% positive predictive value, 98% negative predictive value. Targeted biopsy with SpyGlass yielded 86% sensitivity and 100% specificity. • Stone clearance was achieved in all cases. • Adverse events occurred in 3% of cases.
<p>Ductal Clearance: Occlusion Cholangiogram vs Cholangioscopy</p>	<p>Digital cholangioscopy can detect residual biliary stones missed by occlusion cholangiogram in ERCP</p> <p>Sejpal, Trindade, Lee et al.</p> <p>Endoscopy International 2019; 07 (04): E608-E614</p>	<p>Purpose - Some studies suggest even small stone fragments might act as nidi for future stone formation and recurrent stones. Occlusion Cholangiograms (OC) are performed to confirm ductal clearance but can miss stones. The aim of this study is to assess if digital peroral cholangioscopy (POC) increases the diagnostic yield of stones missed with OC.</p> <ul style="list-style-type: none"> • A total of 96 POC cases were performed on 93 patients meeting the inclusion criteria of dilated bile duct (> 12mm) and/or lithotripsy being performed. • OC was used to initially confirm removal of stones followed by POC. • Using POC, residual stones were found in 34% believed to be free of stones based on OC. • The average bile duct size in cases with residual stones was 15mm. Stones ranging from 1-3mm were found in 41% of these cases, 4-7mm stones in 45% of the cases larger stones were found in 14% of the cases. • Lithotripsy was performed in 13% of the cases and was significantly associated with residual stones • Conclusion: OC can miss residual stones in patients with dilated ducts and those receiving lithotripsy. Digital POC can increase the yield of residual stone detection in these patients and should be considered to confirm ductal clearance.
<p>Migrated Stent Removal:</p>	<p>SpyCatcher: Use of a novel cholangioscopic snare for capture and retrieval of a proximally migrated biliary stent</p> <p>Barakat, Banerjee</p> <p>Digestive Diseases and Sciences (2018) 63:3224-3227</p>	<p>Purpose - Plastic stent migration occurs in 5-10% of patients and, in approximately one-third of these patients, traditional fluoro-guided ERCP methods are not successful (e.g., rat-tooth forceps, polypectomy snares, stone retrieval baskets, etc.). Additionally, guidewire facilitated retrieval techniques are challenging as they require advancement of the guidewire through the stent without direct visualization. This case study details the use of SpyGlass Retrieval Snare to remove a plastic biliary stent.</p> <ul style="list-style-type: none"> • A plastic biliary stent migrated 3-4cm proximal to the ampulla. • Traditional ERCP methods (rat-tooth forceps and polypectomy snare) were unsuccessful • Using SpyScope, the distal portion of the stent was visualized and SpyGlass Retrieval Snare was closed around the flange in the plastic stent, allowing the stent to be pulled into the duodenum • SpyScope was removed and a polypectomy snare was then used to remove the stent from the patient • Conclusion: Cholangioscopy, with the use of SpyGlass Retrieval Snare, offers the advantages of rapid and predictable stent capture and retrieval without the need for fluoroscopy.

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<p>Ductal Clearance:</p> <p>Stone Removal with Spy Basket</p>	<p>Basket Case: Fluoroscopy free capture and retrieval of biliary and pancreatic duct stones</p> <p>Barakat, Banerjee</p> <p>Digestive and Disease Sciences 64, 2776-2779 (2019)</p>	<p>Purpose: Stone extraction necessitating lithotripsy can be complex, with complete duct clearance achieved in approximately half of initial biliary lithotripsy procedures. Pancreatic lithotripsy procedures are even more complex, requiring a median of four procedures for stone eradication. This case study highlights the advantages of the SpyGlass Retrieval Basket in potentially improving ductal clearance capability.</p> <ul style="list-style-type: none"> • A 72-year-old woman presented with profound bile duct dilation. Contrast revealed three filling defects, but fluoroscopic images were limited due to capacious contrast filled duct, which can mask smaller stones. SpyGlass DSTM cholangioscope revealed three yellow-brown stones, each approximately 1cm in diameter, which were successfully removed with SpyGlass Retrieval Basket. Complete ductal clearance was then confirmed via cholangioscopy. • A 68-year-old woman was referred for management of pancreatic stones identified via prior EUS. After multiple EHL treatments to break up the stones, fluoroscopy revealed stones inside branches of the pancreatic duct which could not be removed via balloon sweeps. SpyGlass DSTM cholangioscope was used to visualize the stone and SpyGlass Retrieval Basket was used to grasp and extract the fragments. Ductal clearance was then confirmed with SpyGlass DSTM cholangioscope. • Conclusion: The inefficiency of traditional ERCP based stone extraction methods results in prolonged exposure to radiation for staff, physician and patient. A cholangioscopic approach to stone management offers the advantages of efficient stone removal, minimization of radiation exposure and definitive ductal clearance.
<p>Stone Mgmt:</p> <p>Lithotripsy vs Large Balloon Sphincteroplasty (DASE)</p>	<p>Efficacy of single operator cholangioscopy-guided lithotripsy compared with large balloon sphincteroplasty in management of difficult bile duct stones in a randomized trial</p> <p>Bang, Sutton, Navaneethan, Hawes, Varadarajulu</p> <p>Clinical Gastroenterology and Hepatology</p>	<p>Purpose - An ideal approach to management of difficult bile duct stones is unclear. The aim of this randomized trial was to compare the effectiveness of single operator cholangioscopy guided lithotripsy (SOC-LL) and large balloon sphincteroplasty (LBS) based approaches.</p> <ul style="list-style-type: none"> • Patients with large bile duct stones who failed retrieval using balloons or baskets were randomly assigned to groups that received LBS (N=33) or SOC-LL (N=33). The main outcome measure was single session clearance. • A higher portion of the SOC-LL group had treatment success (93.9%) than the LBS group (72.7%). • Treatment success was significantly associated with SOC-LL, stone to extrahepatic bile duct ration of 1 or less and lack of tapered bile duct. • There were no significant differences in adverse events of SOC-LL (9%) versus LBS (3%) or overall treatment cost (\$16,684 for SOC-LL versus \$10,626 for LBS). • Conclusion: SOC-LL leads to ductal clearance in a significantly higher proportion of patients than LBS, particularly when stone size exceeds diameter of the extrahepatic bile duct. Also, SOC-LL may be required in patients with tapered distal bile duct as LBS alone is less likely to be successful

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<p>Stricture:</p> <p>Factors Impacting Efficacy of SOC</p>	<p>Efficacy of digital single operator cholangioscopy (DSOC) and factors affecting its accuracy in the evaluation of indeterminate biliary strictures</p> <p>Jang, Stevens, Kou, Vargo, Parsi</p> <p>Clinical Endoscopy V91, Issue 2, P385-393.E1 Feb 1, 2020</p>	<p>Purpose: Indeterminate biliary strictures remains a significant diagnostic challenge. The aim of this study was to determine the efficacy of DSOC in evaluation of indeterminate strictures.</p> <ul style="list-style-type: none"> • An observational cohort study was conducted among patients (N = 105) who underwent DSOC for indeterminate biliary strictures at a large tertiary academic medical center. The outcomes of interest were accuracy of DSOC in visual interpretation and bile duct biopsy (DSOC guided). • Diagnostic accuracy was 89.5% for visual interpretation with DSOC and 83.2% for DSOC guided biopsy. • Sensitivity was 89.1% for visual interpretation with DSOC and 69.8% for DSOC guided biopsy. • Specificity was 90% for visual interpretation with DSOC and 97.9% for DSOC guided biopsy. • Among patients with definitive diagnosis of malignancy (N=55 patients), sensitivity of DSOC guided biopsy combined with cytology was 80.6% compared to 47.1% for cytology alone. • Endoscopist experience (fewer than 25 cases) negatively impacted the accuracy of DSOC. • Conclusion: Acquisition of intraductal forceps biopsy samples should be a requisite in evaluation of indeterminate strictures with DSOC.

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