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Cholangioscopy

Clinical data reference guide

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Read the full study
ENDO-1020303-AA

STRICTURES: CHOLANGIOSCOPY BIOPSY VS. BRUSHING

Gerges et al. 2020 Study Summary:

Digital single-operator peroral cholangioscopy-guided biopsy sampling versus ERCP-guided brushing for indeterminate biliary strictures: A prospective, randomized, multicenter trial

Christian Gerges, Torsten Beyna, Raymond S. Y. Tang, Farzan Bahin, James Y. W. Lau, Erwin van Geenen, Horst Neuhaus, Duvvur Nageshwar Reddy, Mohan Ramchandani

Introduction/Summary

This prospective, randomized, multicenter trial compared digital single-operator cholangioscopy (DSOC)-guided biopsy sampling to standard ERCP-guided brushing for diagnosing indeterminate biliary strictures. Accurate diagnosis is critical for guiding treatment decisions in patients with suspected biliary malignancy.

Methodology

- 61 patients with indeterminate biliary strictures based on MRCP were randomized to DSOC-guided biopsy (study arm) or ERCP-guided brushing (control arm)
- DSOC provided direct visualization and targeted biopsy using SpyGlass DS and SpyBite forceps
- ERCP brushing used standard cytology brushes
- Primary endpoint: diagnostic accuracy of first sample
- Secondary endpoints: visual impression accuracy, technical success, adverse events

Key takeaways

DSOC-guided biopsy had significantly higher sensitivity (**68.2%**) than ERCP brushing (**21.4%**) for detecting malignancy

DSOC visual impression showed higher sensitivity (**95.5%**) than ERCP (**66.7%**)

DSOC-guided biopsy had higher overall accuracy (**87.1%**) than ERCP (**65.5%**)

DSOC enabled successful visualization in all cases and impacted patient management in over half the cases

Adverse events were low and comparable between groups

Conclusion

DSOC-guided biopsy is a safe and more effective diagnostic tool than ERCP brushing for evaluating indeterminate biliary strictures. It offers superior sensitivity and visual assessment, supporting its use in tertiary centers for improved patient outcomes.

This study was supported in part by Boston Scientific Corporation through the provision of devices, technical assistance, or an educational grant.
The views and conclusions are those of the authors and do not necessarily reflect those of Boston Scientific Corporation.

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Read the full study
ENDO-2324303-AA

STRICTURES: CHOLANGIOSCOPY BIOPSY VS. BRUSHING

Multicenter Study Summary:

Use of catheter-based cholangioscopy in the diagnosis of indeterminate stenosis: A multicenter experience

Socrate Pallio, Emanuele Sinagra, Alessio Santagati, Fabio D'Amore, Giancarlo Pompei, Giuseppe Conoscenti, Fabio Romeo, Eleonora Borina, Giuseppinella Melita, Francesca Rossi, Marcello Maida, Rita Alloro, Ilaria Tarantino, Dario Raimondo

Introduction/Summary

Indeterminate biliary strictures remain a diagnostic challenge, with up to 20% unresolved after standard evaluation. This multicenter study evaluates the diagnostic utility and safety of catheter-based cholangioscopy using the SpyGlass Direct Visualization System (SDVS) in real-world settings.

Methodology

- Retrospective analysis of 25 consecutive patients with indeterminate biliary strictures across three hospitals
- Procedures performed using SDVS, with visual inspection and biopsy sampling
- Outcomes measured included procedural success, diagnostic accuracy, and adverse events

Key takeaways

SDVS altered clinical outcomes in over 80% of cases

- Procedural success rate: 96%
- Visualization and biopsy success: 96%
- Biopsy diagnosis sensitivity: 100%, specificity: 73%, accuracy: 94.4%
- Only one mild adverse event (cholangitis) reported

Conclusion

Catheter-based cholangioscopy using SDVS is a highly effective and safe diagnostic tool for indeterminate biliary strictures, even in non-referral centers. It offers high diagnostic accuracy and significantly impacts clinical decision-making.

This study was supported in part by Boston Scientific Corporation through the provision of devices, technical assistance, or an educational grant.
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Read the full study
ENDO-2205902-AA

STRICTURES: ASGE GUIDELINES FOR ENDOSCOPIC DIAGNOSIS OF BILIARY STRICTURES

American Society for Gastrointestinal Endoscopy (ASGE) Guideline Summary:

ASGE guideline on the role of endoscopy in the diagnosis of malignancy in biliary strictures of undetermined etiology: Summary and recommendations

Larissa L. Fujii-Lau, Nirav C. Thosani, Mohammad Al-Haddad, Jared Acoba, Curtis J. Wray, Rodrick Zvavanjanja, Stuart K. Amateau, James L. Buxbaum, Audrey H. Calderwood, Jean M. Chalhoub, Nayantara Coelho-Prabhu, Madhav Desai, Sherif E. Elhanafi, Douglas S. Fishman, Nauzer Forbes, Laith H. Jamil, Terry L. Jue, Divyanshoo R. Kohli, Richard S. Kwon, Joanna K. Law, Jeffrey K. Lee, Jorge D. Machicado, Neil B. Marya, Swati Pawa, Wenly Ruan, Mandeep S. Sawhney, Sunil G. Sheth, Andrew Storm, Nikhil R. Thiruvengadam, Bashar J. Qumseya (ASGE Standards of Practice Committee Chair, 2020-2023)

Introduction/Summary

This guideline provides evidence-based recommendations for the endoscopic evaluation of biliary strictures, which are narrowing of the bile ducts due to benign or malignant causes. Accurate diagnosis is critical for appropriate management and prognosis.

Methodology

The guideline was developed by ASGE experts through a comprehensive review of current literature and clinical studies. It includes consensus statements and recommendations based on the strength of evidence and expert opinion.

Key takeaways

- Cholangioscopy and EUS-guided fine needle aspiration/biopsy improve diagnostic yield
- Multidisciplinary approach is recommended for indeterminate strictures
- Initial evaluation should include imaging modalities such as MRCP and CT to assess the location and extent of the stricture
- ERCP remains the cornerstone for tissue sampling and therapeutic intervention
- Brush cytology and forceps biopsy during ERCP are standard techniques, though sensitivity is limited
- Advanced imaging techniques and molecular markers are emerging tools for better characterization

Conclusion

Endoscopic techniques play a vital role in the diagnosis of biliary strictures. Combining imaging, tissue sampling, and advanced modalities enhances diagnostic accuracy. The guideline emphasizes a structured approach to evaluation and the importance of integrating new technologies into clinical practice.

This study was conducted independently and was not sponsored or supported by Boston Scientific Corporation.
The views and conclusions are those of the authors.

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STRICTURES: SELECTIVE CANNULATION

Read the full study
ENDO-875206-AA

Digital single-operator cholangioscopy: A useful tool for selective guidewire placements across complex biliary strictures

Arne Bokemeyer, Dina Gross, Markus Brückner, Tobias Nowacki, Dominik Bettenworth, Hartmut Schmidt, Hauke Heinzow, Iyad Kabar, Hansjoerg Ullerich, Frank Lenze

Introduction/Summary

This study evaluates the effectiveness of digital single-operator cholangioscopy (SOC), specifically the SpyGlass DS System, in facilitating guidewire placement across complex biliary strictures where conventional methods have failed. The technique offers enhanced imaging and maneuverability, potentially reducing the need for invasive procedures.

Methodology

- Retrospective study at University Hospital Muenster (2015-2018)
- 23 patients (30 procedures) with failed conventional guidewire placement
- Digital SOC used to visually guide guidewire placement
- Success defined as enabling balloon dilation and/or endoprosthesis placement
- Safety monitored for pancreatitis, cholangitis, and bleeding

Key takeaways

70% overall success rate for guidewire placement

- Higher success in benign strictures (88.2%) vs. malignant (46.2%)
- Initial procedures more successful (78.3%) than repeated (42.9%)
- 16.7% complication rate (pancreatitis, cholangitis, bleeding), all mild
- Post-SOC interventions: balloon dilation (33.3%), dilation + endoprosthesis (36.7%)

Conclusion

Digital SOC is a valuable tool for guidewire placement in biliary strictures, especially benign ones. It offers a minimally invasive alternative when conventional methods fail and may reduce the need for percutaneous drainage. Despite limitations, this study provides the largest dataset on this topic and supports broader clinical adoption.

This study was supported in part by Boston Scientific Corporation through the provision of devices, technical assistance, or an educational grant.
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STRICTURES: POST LIVER TRANSPLANT

Read the full study
ENDO-23220033-AA

SPYPASS-2 Study Summary:

Digital single-operator cholangioscopy for difficult anastomotic biliary strictures in living donor liver transplant recipients after failure of standard ERCP

In Rae Cho, Sang Hyub Lee, Joongyu Kang, Junyeol Kim, Tae Seung Lee, Myeong Hwan Lee, Min Woo Lee, Jin Ho Choi, Woo Hyun Paik, Ji Kon Ryu, Yong-Tae Kim, Suk Kyun Hong, YoungRok Choi, Nam-Joon Yi, Kwang-Woong Lee, Kyung-Suk Suh

Introduction/Summary

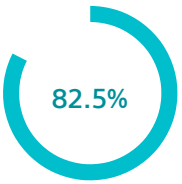
Anastomotic biliary strictures (ABSs) are common complications following living donor liver transplantation (LDLT), often presenting challenges for conventional ERCP due to tight and twisted anatomy. The SPYPASS-2 study evaluates the efficacy and safety of digital single-operator cholangioscopy (SOC) using SpyGlass DS II in LDLT patients with ABSs where standard ERCP failed.

Methodology

- Prospective study at a tertiary center in Korea (Oct 2021 - May 2023)
- Inclusion: 40 LDLT patients with ABSs and failed guidewire placement during ERCP (>10 min)
- Intervention: SOC-assisted guidewire placement and treatment
- Primary endpoint: Technical success (guidewire placement and/or stenting)
- Secondary endpoints: Clinical success, adverse events, reintervention rates

Key takeaways

Technical success (37/40)



Clinical success (33/40)

- Adverse events: Mild cholangitis (10%), pancreatitis (15%), bleeding (2.5%)- Reintervention within 1 month: 10.8%
- SOC time: ~7.3 minutes; Total ERCP time: ~30.7 minutes
- SOC enabled direct visualization and precise guidewire manipulation
- Comparison with historical cohort showed improved outcomes

Conclusion

SOC using SpyGlass DS II is a safe and effective salvage technique for managing difficult ABSs in LDLT patients after failed ERCP. It offers high success rates with minimal complications and may reduce the need for percutaneous interventions. Further studies are warranted to refine patient selection and evaluate cost-effectiveness.

This study was sponsored by Boston Scientific Corporation.
The views and conclusions are those of the authors and do not necessarily reflect those of Boston Scientific Corporation.

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STRICTURES: CHOLANGIOSCOPY FOR DIAGNOSIS

Read the full study
ENDO-1899602-AB

Association between cholangioscopy procedures and cholangiocarcinoma diagnoses: A U.S. county real-world data analysis

Erica Park, Michael J. Cangelosi, Ryoko Sato, David Wilson, Jordan Burlen, Somashekar G. Krishna

Objective

To explore the temporal relationship between cholangioscopy utilization and subsequent cholangiocarcinoma diagnoses across U.S. counties using Medicare data from 2014–2023.

Methodology

- Data Source: 100% Medicare standard analytic files
- Population: Patients diagnosed with cholangiocarcinoma or who underwent cholangioscopy
- Analysis: Zero-inflated poisson regression models
- Focus:
  - Whether prior-year cholangioscopy volumes predict cholangiocarcinoma diagnoses
  - Whether prior-year cholangiocarcinoma diagnoses influence cholangioscopy utilization

Key takeaways

Prior-year cholangioscopy volumes were significantly associated with a **24% increase** in cholangiocarcinoma diagnoses the following year (IRR: 1.239, 95% CI: 1.155–1.328, p<0.001)

- Total cases: 85,909 cholangiocarcinoma diagnoses and 23,902 cholangioscopy procedures across 3,038 counties
- Mean annual county-level volumes:
  - Cholangiocarcinoma: 2.5 cases (SD 7.1)
  - Cholangioscopy: 0.05 procedures (SD 0.25)
- No significant reverse association was found (i.e., prior cholangiocarcinoma diagnoses did not predict cholangioscopy utilization)

Conclusion

Cholangioscopy use is temporally linked to increased detection of cholangiocarcinoma, suggesting its potential role in earlier or more frequent diagnosis. No evidence supports that prior cholangiocarcinoma diagnoses drive increased cholangioscopy use.

This study was supported in part by Boston Scientific Corporation through the provision of devices, technical assistance, or an educational grant.
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STONES: STONE CLEARANCE

Read the full study
ENDO-654611-AA

Maydeo et al. (2019)

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

Amit P. Maydeo, Rungsun Rerknimitr, James Y. Lau, Abdulrahman Aljebreen, Saad K. Niaz, Takao Itoi, Tiing Leong Ang, Jörg Reichenberger, Dong Wan Seo, Mohan K. Ramchandani, Benedict M. Devereaux, Jong Kyun Lee, Mahesh K. Goenka, Randhir Sud, Nam Q. Nguyen, Rakesh Kochhar, Joyce Peetermans, Pooja G. Goswamy, Matthew Rousseau, Surya Prakash Bhandari, Phonthep Angsuwatcharakon, Raymond S. Y. Tang, Anthony Y. B. Teoh, Majid Almadhi, Yun Nah Lee, Jong Ho Moon

Introduction/Summary

This multinational study evaluates the efficacy of peroral cholangioscopy (POCS)-guided lithotripsy for clearing difficult bile duct stones in a single ERCP session. Difficult stones were defined by size (15 mm), impaction, location, or prior failed clearance attempts. The study aimed to assess success rates and safety of POCS-guided electrohydraulic or laser lithotripsy.

Methodology

- Design: Prospective, single-arm, multicenter registry across 17 centers in 10 countries
- Participants: 156 patients with difficult bile duct stones
- Intervention: POCS-guided electrohydraulic or laser lithotripsy using SpyGlass Legacy or DS systems
- Primary endpoint: Stone clearance in a single ERCP session
- Safety monitoring: Adverse events tracked up to 72 hours post-procedure

Key takeaways

POCS impacted patient management in **91%** of cases, avoiding surgery in **53%**

- 80% of patients achieved stone clearance in one procedure
- Success rate was higher for stones ≤30 mm (94%) vs. >30 mm (65%)
- POCS salvaged 78% of prior ERCP failures
- Serious adverse events occurred in 1.9% of patients (pancreatitis, perforation, cholangitis)

Conclusion

POCS-guided lithotripsy is a highly effective and safe method for clearing difficult bile duct stones in a single ERCP session. It may be considered as a first-line therapy to reduce the need for serial procedures and surgery. Further RCTs are warranted to validate cost-effectiveness and refine indications.

This study was sponsored by Boston Scientific Corporation.
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Read the full study
ENDO-875206-AA

STONES: CHOLANGIOSCOPY-GUIDED LITHOTRIPSY

Randomized trial

Efficacy of single-operator cholangioscopy-guided lithotripsy compared with large balloon sphincteroplasty in management of difficult bile duct stones

Ji Young Bang, Bryce Sutton, Udayakumar Navaneethan, Robert Hawes, Shyam Varadarajulu

Background

Endoscopic retrograde cholangiopancreatography (ERCP) is standard for bile duct stone removal. When conventional methods fail, advanced techniques like mechanical lithotripsy (ML), large balloon sphincteroplasty (LBS), and single-operator cholangioscopy-guided laser lithotripsy (SOC-LL) are used. This randomized trial compares SOC-LL and LBS for difficult bile duct stones.

Methodology

- Design: Randomized trial (ClinicalTrials.gov No: NCT00852072)
- Participants: 66 patients with difficult bile duct stones (failed standard ERCP)
- Groups: SOC-LL (n=33) vs. LBS (n=33)
- Primary outcome: Duct clearance in one session
- Secondary outcomes: Adverse events and treatment costs
- Crossover allowed if initial treatment failed

Key takeaways

Treatment success: **SOC-LL 93.9%** vs. **LBS 72.7%** (P=0.021)

- Predictors of Success:
- SOC-LL use (OR 8.7)
- Stone-to-duct ration ≤1 (OR 28.8)
- Absence of tapered bile duct (OR 26.9)
- Adverse Events: SOC-LL 9.1%, LBS 3.0% (all mild)
- Cost: SOC-LL $16,684 vs. LBS $10,626 (P=0.097)

Conclusion

SOC-guided lithotripsy is significantly more effective than LBS for difficult bile duct stones, especially when stone size exceeds duct diameter. LBS may be less effective in patients with a tapered distal bile duct. SOC-LL should be considered first-line in patients with stone/duct ratio >1. Despite higher supply costs, SOC-LL may reduce repeat procedures and overall costs.

This study was supported in part by Boston Scientific Corporation through the provision of devices, technical assistance, or an educational grant.
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OTHER: FLUORO-FREE ERCP

Read the full study
ENDO-1687009-AA

Ridtitid et al. (2023)

Endoscopic clearance of non-complex biliary stones using fluoroscopy-free direct solitary cholangioscopy: Initial multicenter experience

Wiriyaporn Ridtitid, Rungsun Rerknimitr, Mohan Ramchandani, Sundeep Lakhtakia, Raj J Shah, Janak N Shah, Nirav Thosani, Mahesh K Goenka, Guido Costamagna, Mihir S Wagh, Vincenzo Perri, Joyce Peetermans, Pooja G Goswamy, Zoe Liu, Srey Yin, Subhas Banerjee

Introduction/Summary

This multicenter study evaluates the feasibility and safety of fluoroscopy-free direct solitary cholangioscopy (DSC) for the clearance of non-complex common bile duct stones (CBDS). Traditionally, ERCP with fluoroscopy is used, but DSC offers a radiation-free alternative, especially beneficial for pregnant and critically ill patients.

Methodology

- 47 patients with non-complex CBDS were enrolled across 8 tertiary centers in 4 countries
- DSC was used for cannulation, stone visualization, and removal
- Stone clearance was confirmed via cholangioscopy and validated with occlusion cholangiogram
- Follow-up was conducted at 24 hours, 7 days, and 30 days post-procedure

Key takeaways

Complete stone clearance confirmed by DSC and validated by ERCP was achieved in 82.6% of cases

- Fluoroscopy-free cannulation was successful in 89.4% of patients
- Residual stones were detected in 6.5% of cases during validation
- Serious adverse event rate was low (2.1%), with only one case of mild pancreatitis
- The technique was successfully adopted by expert endoscopists within five cases

Conclusion

DSC-assisted stone removal is a feasible and safe alternative to fluoroscopy-guided ERCP for non-complex CBDS. It minimizes radiation exposure and is particularly useful for patients where fluoroscopy is contraindicated. Further randomized studies are warranted to compare DSC with standard ERCP.

This study was supported in part by Boston Scientific Corporation through the provision of devices, technical assistance, or an educational grant.
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Read the full study
ENDO-546321-AA

OTHER: CHOLANGIOPANCREATOSCOPY FOR MAPPING

Multicenter Study Summary:

Digital pancreaticocholangioscopy for mapping of pancreaticobiliary neoplasia: Can we alter the surgical resection margin?

Amy Tyberg, Isaac Raijman, Ali Siddiqui, Urban Arnelo, Douglas G. Adler, Ming-ming Xu, Najib Nassani, Divyesh V. Sejpal, Prashant Kedia, Yun Nah Lee, Frank G. Gress, Sammy Ho, Monica Gaidhane, Michel Kahaleh

Introduction/Summary

This multicenter international study evaluated the role of digital single-operator pancreaticocholangioscopy (D-SOPC) as a presurgical mapping tool to delineate the extent of pancreaticobiliary neoplasia. The goal was to determine whether D-SOPC could influence surgical planning and optimize patient care.

Methodology

- 118 patients from 9 international centers were included
- Patients had pancreaticobiliary lesions and were anticipating surgery
- D-SOPC was performed using SpyGlass Digital system
- Primary outcome: whether D-SOPC altered the surgical plan
- Secondary outcomes: correlation between endoscopic and surgical histology, need for additional interventions, and adverse events

Key takeaways

- 34% of patients had their surgical plan altered based on pancreatocholangioscopy

In the bile duct:

- **6 patients** had less extensive surgery
- **26** avoided surgery

In the pancreatic duct:

- **4** had more extensive surgery
- **4** had less extensive surgery

- Overall correlation between endoscopic and surgical histology was 88%
- Adverse events were minimal (2.5% post-ERCP pancreatitis, all managed conservatively)
- D-SOPC provided effective visualization and biopsy capability to guide surgical decisions

Conclusion

Digital pancreaticocholangioscopy is a valuable tool for presurgical mapping of pancreaticobiliary neoplasia. It can influence surgical planning and potentially reduce unnecessary or overly extensive procedures. Further prospective studies are needed, especially when considering surgical downstaging.

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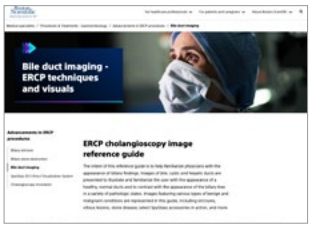
ADDITIONAL CHOLANGIOSCOPY RESOURCES

Celebrating cholangioscopy innovation

In this episode of GI EndoCast, hear Dr. Raijman discuss his perspective on the evolution of cholangioscopy and how he incorporates it into his clinical practice.

Clinical application guide

Download the Clinical Application Guide to review the data that demonstrates how the SpyGlass DS II Direct Visualization System allows you to see and enable diagnosis and treatment of bile duct disease.



Cholangioscopy image reference guide

Images featuring various types of benign and malignant conditions are represented in this guide, including strictures, villous lesions, stone disease, select SpyGlass accessories in action, and more.

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