

DISPOSITIVO DE COLANGIOSCOPIA DIRECTA SPY GLASS Y LITOTRICIA AUTOLITH TOUCH ENERO 2020

Título del documento	Dispositivo de colangioscopia directa y litotricia: <ul style="list-style-type: none">• SpyGlass Direct Visualization System; Boston Scientific, Marlborough, MA• Sistema de litotricia electrohidráulica Autolith touch
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1. INTRODUCCIÓN

La colangiopancreatografía retrógrada endoscópica (CPRE) es la principal herramienta diagnóstica y terapéutica para las enfermedades de las vías biliares, utiliza fluoroscopia para visualizar el árbol biliar.

Existen varias situaciones clínicas en las que los métodos establecidos para la evaluación de lesiones biliopancreáticas (estenosis, quiste, tumor, defecto de relleno) no son informativos. La distinción entre una enfermedad benigna y una maligna sigue siendo un desafío para la CPRE, y la precisión de las muestras citológicas e histológicas, obtenidas bajo guía fluoroscópica, en ocasiones es insatisfactoria.

En el caso de cálculos biliares intraductales, entre el 5 y el 10% de los casos, no pudieron ser resueltos por la CPRE, incluso después de la dilatación endoscópica papilar con balón grande (EPLBD) y la litotricia mecánica (ML).

Debido a la necesidad de mejorar el diagnóstico y la terapia mínimamente invasiva de los trastornos de las vías biliares, se han desarrollado nuevas tecnologías para la colangioscopia.

La colangioscopia peroral (POCS) se ha convertido en una importante herramienta diagnóstica y terapéutica para evitar la cirugía agresiva e innecesaria en muchos escenarios clínicos. La POCS fue descrita por primera vez en la década de 1970, y hasta ahora tenía muchas limitaciones que impedían que se convirtiera en un procedimiento rutinario en la práctica diaria de la endoscopia. Estas limitaciones son: necesitar dos endoscopistas experimentados para el sistema madre-hija, los endoscopios disponibles son frágiles, difíciles de instalar, con una maniobrabilidad limitada (deflexión de la punta de dos vías), una calidad de imagen deficiente y un tiempo de procedimiento prolongado. La intubación del conducto biliar común (DBC) con los endoscopios ultrafinos que se utilizan para la colangioscopia oral directa a menudo es difícil debido al asa en el estómago y a la necesidad de una esfinterotomía grande o dilatación con balón, asociada con más eventos adversos. En ocasiones, la inserción profunda en el conducto biliar no es posible a pesar del uso de guías o globos de anclaje. Con la idea de superar estas limitaciones surge un nuevo dispositivo para la colangioscopia digital con un solo operador (D-SOC).

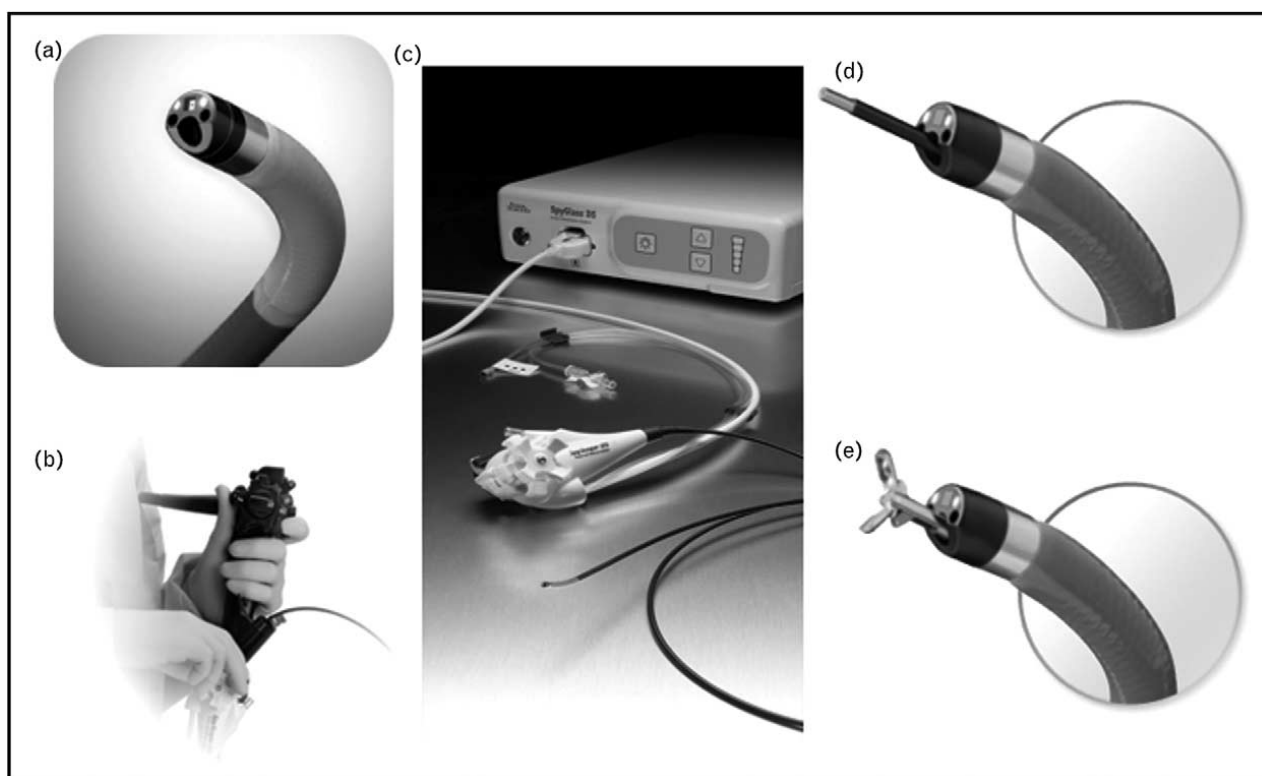
La innovación en la colangioscopia peroral directa llevó al desarrollo del sistema de visualización directa POCPs SpyGlass TM de un solo operador (Boston Scientific Corporation), que fue autorizado para su uso clínico en los EE.UU. en 2005.

El sistema Spy Glass es un dispositivo diseñado para la visualización endoscópica de la vía biliar y pancreática, lo que mejora la caracterización de lesiones, permite dirigir las biopsias o facilitar la canalización selectiva del árbol biliar, además de procedimientos terapéuticos como son la litotricia de grandes litiasis o la radiofrecuencia de tumores de la vía biliar.

Los procedimientos para los que se utilizaría este nuevo dispositivo según la solicitud serían:

- 1- Litotricia en litiasis de gran tamaño refractarias a tratamiento por CPRE convencional.
- 2- Estudio de estenosis de la vía biliar o pancreática: permite toma de biopsias
- 3- Cateterización selectiva de conductos biliares.
- 4- Terapéutica que precise control visual: extracción de prótesis biliares retenidas, captura de pólipos biliares, radiofrecuencia de tumores, caracterización de estenosis anastomóticas en transplantados hepáticos, etc

Las diferencias entre el sistema Spy Glass y la CPRE, la técnica endoscópica convencional para lesiones biliopancreáticas es que en la CPRE no hay visión directa. Con el microendoscopio digital o sonda de un solo uso Spy Scope DS Catéter, del procesador Spy Glass, se consigue ver directamente las vías biliopancreáticas y se puede hacer un diagnóstico diferencial entre lesiones, realizar biopsias de una manera dirigida y directa y ofrecer un tratamiento según la patología diagnosticada. Esta técnica suele requerir de papilotomía, siendo imprescindible la realización CPRE en un primer tiempo. Por lo tanto, no son técnicas mutuamente excluyentes en todos los casos.



Sistema digital SpyGlass con un SpyScope optimizado^(a), acoplado al duodenoscopio^(b), y con un simple sistema de conexión^(c). Accesorios: una sonda electrohidráulica^(d) o pinzas de biopsia SpyBite^(e).

El sistema de visualización directa Spy Glass consta de:

- El equipo fundamental: SpyGlass DS Digital Controller:
 - Cámara SpyGlass PAL
 - Monitor de vídeo SpyGlass
 - Carro de componentes SpyGlass. El brazo de 3 articulaciones (sin abrazadera) está incluido con el carro de componentes El brazo de 3 articulaciones con abrazadera resulta útil si no se compra el carro de componentes, ya que permite el montaje del brazo en cualquier otro carro o mesa
 - Fuente de luz SpyGlass
 - Cable de luz SpyGlass
 - Ocular SpyGlass
 - Transformador de aislamiento 230 V
 - Bomba de irrigación con interruptor de pedal
 - Bandeja de almacenamiento SpyGlass – Grande
 - Bandeja de almacenamiento SpyGlass – Pequeña

- Cables de alimentación
- SpyGlass™ Accesorio Reutilizable: sonda de visualización directa SpyGlass. La sonda SpyGlass se ha validado para 20 ciclos de desinfección sin degradación de imagen. Sin embargo, el número real de utilizaciones depende del modo en que se maneje la sonda SpyGlass. Las fibras ópticas son muy sensibles y se deben manejar con cuidado.
- SpyGlass™ DS Accesorios de un solo uso:
 - Catéter de acceso y de introducción SpyScope™ DS
 - Pinzas de biopsia SpyBite™
 - Tubos de irrigación SpyGlass
- SpyGlass™ Accesorios opcionales:
 - Brazo de 3 articulaciones con abrazadera
 - Bombilla de repuesto para la fuente de luz SpyGlass

El catéter SpyScope DS tiene 10 french de grosor y 214 cm de longitud, se introduce a través de un duodenoscopio con canal de trabajo terapéutico. El extremo distal es flexible y sus movimientos se controlan con dos mandos situados en el extremo proximal. El catéter SpyScope es un dispositivo de un solo uso, controlado por un solo operador, diseñado para facilitar el acceso a la anatomía pancreático-biliar tanto para los procedimientos diagnósticos como los terapéuticos. El catéter SpyScope se compone de un mango de control que se acopla a cualquier duodenoscopio estándar y un catéter de colocación largo y flexible que se inserta por el canal de trabajo del duodenoscopio y pasa directamente más allá de la ampolla en la anatomía pancreático-biliar. Este diseño permite que un solo médico opere simultáneamente ambos osciloscopios. El ángulo de visión es de 120°. La sonda tiene dos puntos de luz LED, dos conductos internos para irrigación de agua pues la visión es bajo inmersión y un canal de trabajo que permite el paso de material accesorio común (guías metálicas) o específico (pinzas de biopsia, asas de polipectomía o sondas de litotricia) para realizar procedimientos intervencionistas y tiene una salida para conectar aspiración.

La sonda va conectada a su propio procesador óptico digital SpyGlass™ DS controller, que se integra en la torre de endoscopia convencional utilizando el monitor de esta para la visualización evitando la necesidad de un segundo monitor.

El dispositivo SpyScope y los accesorios se adquieren como material fungible, de un sólo uso y el procesador digital SpyGlass es reutilizable.

En el formulario de solicitud de esta nueva tecnología, se solicita también el dispositivo electrohidráulico Autolith® Touch que comercializa la misma empresa ya que para una de las indicaciones del Spy Glass, la litotricia, se requiere un litotriector y una sonda de litotricia como fungible.

Este nuevo sistema, se denomina litotricia intraductal electrohidráulica, su ventaja principal es que permite visualizar a través del endoscopio las vías biliares y, al mismo tiempo, destruir los cálculos. Durante la intervención, dentro del mismo endoscopio hay una sonda que envía pequeñas descargas eléctricas capaces de fragmentar los cálculos de gran tamaño que no pueden eliminarse de los conductos biliares con la CPRE convencional y permitir su posterior extracción. Comparada con la cirugía convencional esta nueva técnica es más económica, ya que no requiere ingreso en muchos casos. El

procedimiento se realiza en una hora aproximadamente y el paciente puede volver a su casa el mismo día.

2. ¿ES UNA PRESTACIÓN DE LA CARTERA DE SERVICIOS DEL SISTEMA NACIONAL DE SALUD?

Podría incluirse dentro de endoscopia digestiva, aunque esta es una técnica mucho más específica que debería citarse expresamente:

ANEXO III Cartera de servicios comunes de atención especializada

5. Indicación o prescripción, y la realización, en su caso, de procedimientos diagnósticos y terapéuticos

5.2 Otros procedimientos diagnósticos y terapéuticos

5.2.7 Endoscopias

3. ¿ESTÁ CONSIDERADA UNA TECNOLOGÍA SANITARIA (TS) EMERGENTE PROPUESTA PARA SU PRIORIZACIÓN Y EVALUACIÓN DENTRO DE LA COMISIÓN DE PRESTACIONES ASEGURAMIENTO Y FINANCIACIÓN (CPAF) DE LA SUBDIRECCIÓN GENERAL DE CALIDAD Y COHESIÓN DEL MSSSI?

No está considerada una tecnología sanitaria emergente propuesta para evaluación en 2020. Ni tampoco se ha priorizado para que la Red de Agencias de Evaluación de Tecnologías Sanitarias realice un informe de evaluación para el año 2020.

4. ¿HAY INFORME DE EVALUACIÓN REALIZADO POR UNA AGENCIA DE EVALUACIÓN DE TS O REVISIONES SISTEMÁTICAS DE LA LITERATURA?

Se realizaron tres búsquedas en la literatura científica siguiendo la metodología para búsquedas rápidas:

1. [NHS Centre for Reviews and Dissemination \(CRD\)](#) que incluye
 - a. [-DARE \(Database of Abstracts of Reviews of Effects\)](#): contiene resúmenes de artículos que valoran y sintetizan RS de efectividad.
 - b. [-NHS EED](#): contiene resúmenes de artículos sobre evaluaciones económicas de intervenciones en atención sanitaria.
 - c. [-HTA \(Health Technology Assessment\)](#): contiene informes de evaluación de tecnologías sanitarias e información de proyectos en curso realizados por las mismas agencias.
 - d. [-INAHTA](#): informes de otras agencias o unidades de Evaluación de Tecnologías Sanitarias. Incluye los informes de la Red Española de Agencias de EvTS.
 - e. [-EuroScan International Network](#): informes de tecnologías nuevas y emergentes.
2. [Biblioteca Cochrane Plus](#)
3. [Embase](#)

Palabras clave: Spy Glass, Digital single-operator cholangioscopy

Fechas de búsqueda: 2016-2019

Idiomas: inglés y español.

Tras la búsqueda bibliográfica se obtuvieron los siguientes documentos:

En NHS Centre for Reviews and Dissemination (CRD) no se encontró ningún informe de evaluación de este nuevo dispositivo.

En Cochrane, se localizaron 17 ensayos clínicos, uno se descartó por no referirse al Spy Glass. De los 16 restantes, 7 están inscritos en la Cochrane Central Register of Controlled Trials (CENTRAL) pero no tienen resultados publicados aún, 2 han sido publicados y 7 se han presentado resultados preliminares en jornadas de la especialidad (uno es el mismo presentado en el congreso europeo y en el americano), por lo que se descartaron aunque sí los hemos incluido en la bibliografía.

En Embase se encontraron 33 artículos. Cuatro se descartaron por no coincidir con la búsqueda, dos se descartaron por estar en otros idiomas y seis se descartaron por no tener abstract. Tres coincidían con los encontrados en la búsqueda en Cochrane. En total quedaron 18 artículos.

Búsqueda Cochrane:

[Randomized study of digital single operator cholangioscope compared to fiberoptic single operator cholangioscope in a novel cholangioscopy bench model](#) Shah R.J., Neuhaus H., Parsi M., Reddy D.N., Pleskow D.K. *Endoscopy International Open* 2018 6:7 (E851-E856)¹

Background and study aims

Cholangiopancreatography is utilized for diagnosis and therapy of pancreaticobiliary disorders. a fully-disposable, digital, single-operator cholangioscope (DSOC) was developed with high image resolution and wide field-of-view. This bench study compared the new DSOC to the previous semi-disposable, fiber-optic cholangioscope (FSOC) prior to the clinical availability of the DSOC system.

Methods

Five experts performed one practice run followed by randomized runs comparing DSOC to FSOC in a biliary tract model consisting of three fixed left-intrahepatic tracts (LIHD), and variable common bile duct (CBD) and right-intrahepatic tracts (RIHD) with seven total lesions in multiple configurations. Timed runs aimed to visualize and target each lesion using miniature biopsy forceps. Definitions: visual success, visualizing targets; targeting success, touching target with forceps; complete run, touching seven targets within 20 minutes. Image quality, ease-of-use, and time to completion were recorded.

Results

Thirty-seven evaluable runs (20 DSOC, 17 FSOC) were completed. DSOC was superior to FSOC in Visual (99% vs. 67%, $P < 0.001$) and targeting success (6.6 vs. 4.5, $P = 0.009$), proportion of complete runs (13/20 vs. 0/17, $P < 0.001$) and time of run (10.1min vs. 15.4min, $P < 0.001$). For fixed LIHD, DSOC achieved higher targeting success compared to FSOC (2.6 vs. 1.1, $P < 0.001$) with no difference in RIHD and CBD targets (4.0 vs. 3.4, $P = 0.39$). Investigators reported superior image quality and ease-of-use with DSOC.

Conclusions

In this model, DSOC performed superiorly to FSOC in image quality, visualization, and maneuverability. The model could potentially be utilized for training endoscopists less experienced with cholangiopancreatography.

Digital, single-operator cholangiopancreatography in the diagnosis and management of pancreaticobiliary disorders: a multicenter clinical experience (with video). Navaneethan U, Hasan MK, Kommaraju K, Zhu X, Hebert-Magee S, Hawes RH, Vargo JJ, Varadarajulu S, Parsi MA. *Gastrointestinal endoscopy*, 2016, 84(4), 649-655.²

Background and Aims:

Digital cholangioscopes provide higher-resolution imaging of the pancreatobiliary tract compared with fiberoptic instruments. The role of a new, digital, single-operator cholangiopancreatography (SOC) system for diagnosis and treatment of pancreatobiliary disorders in clinical practice is not known.

Methods:

We performed a multicenter, observational study of 105 consecutive patients with suspected pancreatobiliary disorders. The main outcome measures were (1) sensitivity and specificity of SOC visual appearance and biopsies in the diagnosis of indeterminate biliary strictures and (2) achieving complete duct clearance in patients with biliary or pancreatic duct stones.

Results:

A total of 98 cholangioscopy and 7 pancreatoscopy procedures were performed in 105 patients. Superior views of the ductal lumen and mucosa were obtained in all 44 patients with indeterminate biliary strictures. Among the 44 patients who underwent SOC-guided biopsies, the specimen was adequate for histologic evaluation in 43 patients (97.7%). The sensitivity and specificity of SOC visual impression for diagnosis of malignancy was 90% (95% confidence interval [CI], 69.9%-97.2%) and 95.8% (95% CI, 79.8%-99.3%), respectively. The sensitivity and specificity of SOC-guided biopsies for diagnosis of malignancy was 85% (95% CI, 64.0%-94.8%) and 100% (95% CI, 86.2%-100%). In patients with biliary or pancreatic duct stones (N = 36), complete duct clearance with stone removal in 1 session was accomplished in 86.1% of patients (31/36). Three patients (2.9%) experienced SOC-related adverse events that included cholangitis in 2 patients and postprocedure pancreatitis in 1 patient.

Conclusions:

SOC has become an integral part of the ERCP armamentarium and has high accuracy in the evaluation of indeterminate biliary strictures. Complete stone clearance was achieved in all but 1 patient with challenging biliary or pancreatic duct stones.

Resto de artículos con resultados preliminares presentados en Congresos y Jornadas

Procedural success and Impact on patient management of single operator cholangioscopy using SpyGlas™/SpyGlas™ DS-Interim results from a large multi-national registry. YN Lee, JH Moon, A Maydeo, M Ramchandani, T Itoi, R Rerknimitr, D Seo, MK Goenka, J Lau, S Niaz, JK Lee. Journal of gastroenterology and hepatology (australia). Conference: asia pacific digestive week, APDW 2016. Japan. Conference start: 20161102. Conference end: 20161105, 2016, 31, 269³

The ideal technique for processing SpyBite™ tissue specimens: a prospective, single-blinded, pilot study of histology and cytology techniques. M Keegan, R Theyventhiran, J Kench, E Farrell, P Saxena, A Kaffes. Journal of gastroenterology and hepatology (australia). Conference: australian gastroenterology week 2016. Australia. Conference start: 20161010. Conference end: 20161012, 2016, 31, 39-40⁴

Prospective evaluation of digital single operator cholangioscope for diagnostic and therapeutic procedures. A Okuda, T Ogura, A Miyano, N Nishioka, M Imanishi, W Takagi, S Onda, T Sano, M Amano, A Imoto, D Masuda, K Higuchi. Gastrointestinal endoscopy, 2018, 87(6), AB203-⁵

Spyglass percutaneous transhepatic cholangiography-guided lithotripsy of large or multiple gallstones in patients with altered surgical anatomy. CJ Cooper, B Aslam, ER Salas, A Al Ghanoudi, D Raissi, HE Mardini, WM Frandah. Gastrointestinal endoscopy, 2018, 87(6), AB213-AB214⁶

Proposal of a macroscopic classification for tissular lesions of the bile duct detected during peroral cholangioscopy (POCS) C Robles-Medranda, M Soria-Alcivar, M Valero, M Puga-Tejada, R Oleas, H Alvarado-Escobar, J Ospina-Arboleda, H Pitanga-Lukashok. American journal of gastroenterology, 2017, 112, S6-S7⁷

Efficacy of digital cholangioscopy-guided laser lithotripsy versus mechanical lithotripsy in patients with very large common bile duct stone(s) who failed papillary large balloon dilation: a randomized controlled study S Kulpatcharapong, W Ridditid, P Angsuwatcharakon, P Piyachaturawat, P Kongkam, C Boonmee, W Pareesri, T Ratanachu-Ek, R Rerknimitr *Gastrointestinal endoscopy*, 2018, 87(6), AB57⁸

Proposal of a macroscopic classification for tissular lesions of the bile duct detected during per oral cholangioscopy (POCS). C Robles-Medranda, M Soria, M Valero, M Puga, H Alvarado, J Ospina, H Pitanga Lukashok. *United european gastroenterology journal*, 2016, 4(5), A48-⁹

Búsqueda Embase:

Management of malignant biliary diseases by the use of peroral and percutaneous cholangioscopy Alshati A., Kurli V., Wittenberg A., Patel G., Kachaamy T. *VideoGIE* 2019 4:9 (431-435)¹⁰

Background and Aims:

The single-operator digital cholangioscope has allowed visual access to the biliary tree and the ability to perform selective biopsies. This has significantly improved our diagnostic yield in bile-duct disorders. Cholangioscopy requires specialized equipment and expertise. It is especially challenging in altered anatomy for various reasons, including difficulty in accessing the biliary tree, difficulty in maintaining endoscope position, and difficulty in using ERCP specialized tools. In addition, the use of cholangioscopy in interventional procedures has been very limited. In this video, we demonstrate some of the diagnostic and therapeutic uses of percutaneous cholangioscopy in patients with altered anatomy of the biliary tree.

Methods:

Percutaneous cholangioscopy was performed in 3 different procedures in 2 patients with altered anatomy of the biliary tree. The first was for the diagnosis of a distally located malignant biliary stricture, the second was for management of hemobilia, and the third was for biliary stent placement.

Results:

Technical and clinical success was achieved in all 3 situations. There were no procedure-related adverse events.

Conclusion:

The use of percutaneous cholangioscopy in altered anatomy for diagnostic and therapeutic uses is safe and effective and may prove very useful in selected unusual conditions.

Management of difficult bile duct stones and indeterminate bile duct structures: Reduced ERCP radiation exposure with adjunct use of digital single-operator cholangioscopy Tsapaki V., Papastergiou V., Giannakopoulos A., Angelogiannopoulou P., Delatolas V., Triantopoulou S., Theocharis S., Paraskeva K. *Physica Medica* 2019 64 (69-73)¹¹

Introduction:

Endoscopic Retrograde Cholangio-Pancreatography (ERCP) is an well-established endoscopic procedure for the management of biliary diseases. The use of fluoroscopy during ERCP has often raised concerns regarding potential risks from radiation exposure, particularly in complex cases. We investigated whether a new digital single-operator cholangioscopy (D-SOC) system, used adjunctively to ERCP, actually reduces patient radiation exposure.

Materials and methods:

We retrospectively analyzed a prospective database (April 2016 to October 2018) including consecutive patients who underwent successful management of difficult-to-treat biliary stones or indeterminate biliary strictures by using either conventional ERCP (ERCP cohort) or ERCP in conjunction with D-SOC (ERCP/D-SOC cohort). The overall patient radiation exposure outcomes were compared in terms of Kerma Area Product (KAP), Fluoroscopy time (T) and the total number of films (F).

Results:

Overall, 47 patients (mean 71.8 years, 59.6% males) were included (ERCP cohort = 29, ERCP/D-SOC cohort = 18), referred either for difficult bile duct stones (n = 36) or indeterminate biliary strictures (n = 11). The median KAP, T and F in the ERCP/D-SOC cohort were 12.3 Gy cm^2 , 3.7 min and 4 films respectively, compared with 52.1 Gy cm^2 , 8.4 min, and 5 films respectively in the ERCP cohort. Statistically significant differences (P = 0.0001) were found for KAP and T.

Conclusions:

Adjunct use of a digital cholangioscopy platform appears to significantly reduce radiation exposure in patients undergoing ERCP for the management of difficult bile stones or indeterminate biliary strictures.

*Advances in Endoscopic Imaging of the Biliary Tree Mukewar S., Carr-Locke D. Gastrointestinal Endoscopy Clinics of North America 2019 29:2 (187-204)*¹²

Direct endoscopic imaging of the biliary tree is increasingly performed by endoscopists since the introduction of digital single-operator cholangioscopy. In parallel, there have been several advances to overcome the challenges associated with direct peroral cholangioscopy with development of multibending cholangioscopes and new devices to enable direct placement of an endoscope into the biliary tree without a supporting duodenoscope. The indications for cholangioscopy are also evolving with newer indications, such as intraductal lithotripsy, foreign body (mostly stent) removal, guide wire cannulation of specific ducts, photodynamic therapy for cholangiocarcinoma, and performance of fluoroscopy-free cholangiography. There has also been progress in image enhancement during cholangioscopy and additional imaging techniques, such as intraductal ultrasound, confocal laser endomicroscopy, and optical coherence tomography.

*Digital single-operator cholangioscopy: a useful tool for selective guidewire placements across complex biliary strictures. Bokemeyer A., Gross D., Brückner M., Nowacki T., Bettenworth D., Schmidt H., Heinzow H, Kabar I., Ullerich H., Lenze F. Surgical Endoscopy 2019 33:3 (731-737)*¹³

Background:

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.

Methods:

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.

Results:

In total, 30 examinations with a digital SOC-assisted guidewire placement across biliary strictures, performed in 23 patients, were identified. In 52% of all patients, the stricture was benign with post-liver-transplant strictures (75%) as the most frequent finding; in 48% of all patients the stricture was malignant with cholangiocellular carcinoma as the most frequent type (64%). Guidewire placement was successful in 21 of 30 procedures (70%). According to a subgroup analysis, digital 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). Furthermore, the technical success rate tended to be increased in cases of initial examinations (78.3%) than in patients with repeated examinations (42.9%; p = 0.15). Adverse events, such as post-interventional pancreatitis or cholangitis as well as severe bleeding occurred in 16.7% of all examinations.

Conclusions: 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.

Comparison of digital versus fiberoptic cholangioscopy in patients requiring evaluation of bile duct disease or treatment of biliary stones. Dimas I.D., Vardas E., Papastergiou V., Fragaki M., Velegaki M., Mpitouli A., Voudoukis E., Theodoropoulou A., Giannikaki E., Chlouverakis G., Paspatis G.A. *Annals of Gastroenterology* 2019 32:2 (199-204)¹⁴

Background:

Recently, the introduction of the novel digital SpyGlass™ DS Direct Visualization system (Boston Scientific Corp., Natick, MA, USA) has signaled the transition into the era of digital single-operator cholangioscopy (D-SOC). We sought to compare the clinical utility between fiberoptic single-operator cholangioscopy (F-SOC) and D-SOC in a tertiary-care referral center in Greece.

Methods:

This was a retrospective analysis of a prospective database of single-operator cholangioscopy (SOC) procedures performed over an 8-year period (2009-2017) at a single tertiary-care referral center. The study population consisted of consecutive adults referred for cholangioscopy for a variety of clinical indications, including biliary strictures, difficult biliary stones and migrated or occluded pancreatic or biliary stents.

Results:

A total of 2763 endoscopic retrograde cholangiopancreatography procedures were performed during the study period. Overall, SOC was performed in 68 (2.46%) procedures (F-SOC=39, D-SOC=29), showing a significant increase in the utilization of cholangioscopy during the D-SOC (29/599; 4.84%) compared with the F-SOC (39/2124; 1.83%) period ($P=0.0001$). The overall technical success of diagnostic SOC was 69.1% (38/55), being marginally higher for D-SOC (83.3%) than for F-SOC (58.1%), although not reaching statistical significance ($P=0.07$).

Conclusions:

D-SOC was utilized more frequently in our tertiary-care non-academic referral center, demonstrating a favorable safety profile and a trend towards a marginally higher technical success rate for the diagnosis of biliary strictures compared with F-SOC.

Digital cholangioscopy: the diagnostic yield and impact on management of patients with biliary stricture. Urban O., Evinová E., Fojtík P., Loveček M., Kliment M., Zoundjiekpon V., Falt P. *Scandinavian Journal of Gastroenterology* 2018 53:10-11 (1364-1367)¹⁵

Objectives:

Biliary strictures frequently present a diagnostic challenge. The aim of this study was to evaluate the impact of digital single-operator cholangioscopy (DSOC) on subsequent treatment of patients with biliary stricture.

Methods:

Consecutive patients undergoing DSOC for biliary stricture were enrolled. Gold standard for final diagnosis included histology from surgical resection. In patients without surgery, clinical evaluation methods and repeated imaging studies were used for comparison of DSOC findings and final diagnosis. Patients were followed-up prospectively focusing on subsequent treatment.

Results:

Among 30 enrolled patients, final diagnosis was malignant in 13 (43%) and benign in 17 (57%). The sensitivity and specificity of visual impression in diagnosing malignant stricture were 100% (95% CI: 75 – 100) and 76% (95% CI: 50 – 93), respectively. The sensitivity and specificity for biopsy were 92% (95% CI: 62 – 100) and 100% (95% CI: 78 – 100), respectively. One (3%) case of complicating cholangitis with fatal outcome occurred. Final treatment included surgery in 7 (23%), endoscopy in 18 (60%) and chemotherapy in 3 (10%) of patients.

Conclusions:

In this study, favorable operating characteristics of DSOC were confirmed. Absolute negative predictive value of visual impression provided reassurance to patients with benign strictures who avoided unnecessary surgery in 53%. One (3%) case of cholangitis with fatal outcome occurred.

Current role of endoscopic cholangioscopy. Derdeyn J., Laleman W. *Current opinion in gastroenterology* 2018 34:5 (301-308)¹⁶

Purpose of review:

Every year more than one million people worldwide undergo an endoscopic retrograde cholangiopancreatography (ERCP) for disorders of the bile duct system. This review aims to discuss recent clinical data with regard to single-operator peroral cholangioscopy (POC).

Recent findings:

Innovations and technical optimizations of POC devices have extended diagnostic and therapeutic options for patients with complex biliary disease. Most of the currently available clinically relevant data are obtained with the single-operator peroral cholangioscopy (SOC)-system SpyGlass, which in a period of a decade has evolved further to a digital platform with increasing applicability, usefulness and cost-effectiveness. SUMMARY: POC allows endoscopists to treat patients with complicated diseases of the gallbladder, liver, biliary tract, and pancreas better. In recent years, this technique was optimized to overcome prior limitations. The implementation of the single-operator SpyGlass Digital System in daily practice becomes a reality. We make an overview of the history of cholangioscopy, the technical evolution, and usefulness of this platform and take a look at its economic impact.

Safety, diagnostic accuracy and therapeutic efficacy of digital single-operator cholangioscopy Lenze F., Bokemeyer A., Gross D., Nowacki T., Bettenworth D., Ullerich H. *United European Gastroenterology Journal* 2018 6:6 (902-909)¹⁷

Background:

Digital single-operator cholangioscopes (digital SOCs), equipped with an improved image quality, have been recently introduced.

Objective:

The aim of this study is to evaluate the safety and diagnostic and therapeutic efficacy of digital SOCs (Spyglass™ DS).

Methods:

Sixty-seven digital SOC procedures performed between 2015 and 2017 were retrospectively analyzed.

Results:

The most frequent indications for examination were indeterminate biliary strictures (61.2%) and biliary stone disease (23.9%). In 25 patients (37.3), visual findings predicted malignancy with a sensitivity of 88.9%, a specificity of 97.6%, a positive predictive value (PPV) of 96.0% and a negative predictive value (NPV) of 92.9%. For histological analysis, forceps biopsies were performed in 29 patients (43.2%). Compared with visual findings, forceps biopsies yield a lower diagnostic efficacy in diagnosing malignancy (sensitivity 62.5%, specificity 90.0%, PPV 90.9%, NPV 60.0%). Therapeutic interventions were performed in 19 patients with a technical success rate of 89.4%. Adverse events were observed in 17 patients (25.4%). Of these, 11 patients (16.4%) suffered from severe adverse events (pancreatitis, cholangitis or major bleeding), which led to a prolonged hospital stay.

Conclusion:

Digital SOCs have excellent diagnostic and therapeutic efficacies, but are accompanied by high rates of adverse events; therefore, physicians should use digital SOCs in carefully selected cases.

Electrohydraulic lithotripsy for difficult bile duct stones under endoscopic retrograde cholangiopancreatography and peroral transluminal cholangioscopy guidance. Kamiyama R., Ogura T., Okuda A., Miyano A., Nishioka N., Imanishi M., Takagi W., Higuchi K. *Gut and Liver* 2018 12:4 (457-462)¹⁸

Background/Aims:

Electrohydraulic lithotripsy (EHL) under endoscopic retrograde cholangiopancreatography (ERCP) guidance can be an option to treat difficult stones. Recently, a digital, single-operator cholangioscope (SPY-DS) has become available. Peroral transluminal cholangioscopy (PTLC) using SPY-DS has also been reported. In this retrospective study, the technical feasibility and clinical effectiveness of EHL for difficult bile duct stones under ERCP guidance and under PTLC guidance was examined.

Methods:

In this pilot study, patients with difficult bile duct stones between July 2016 and July 2017 were retrospectively enrolled.

Results:

Forty-two consecutive patients underwent EHL using a SPY-DS; 34 patients underwent EHL under ERCP guidance, and the other 8 patients underwent EHL under PTLC guidance. Median procedure time was 31 minutes (range, 19 to 66 minutes). The median number of EHL sessions was 1 (range, 1 to 2), and that of ERCP sessions was also 1 (range, 1 to 3). The rate of complete stone clearance was 98% (41/42). Adverse events such as cholangitis and acute pancreatitis were seen in 14% (6/42), which could be treated conservatively.

Conclusions:

EHL using SPY-DS was technically feasible, not only under ERCP guidance, but also PTLC guidance. A prospective clinical study of EHL using SPY-DS is needed.

Mirizzi's syndrome in Roux-en-Y bypass patient successfully treated with cholangioscopically-guided laser lithotripsy via percutaneous gastrostomy. Hammoudi N., Brieau B., Barret M., Bordacahar B., Leblanc S., Coriat R., Chaussade S., Prat F.. *Endoscopy International Open* 2018 6:7 (E826-E829)¹⁹

Obesity and bariatric surgery are major risk factors in gallstone disease. In patients with a past history of Roux-en-Y gastric bypass, Mirizzi's syndrome is a challenging endoscopic situation because of the modified anatomy. Here we report the first case of a patient with a Roux-en-Y gastric bypass treated by intracorporeal lithotripsy with a digital single-operator cholangioscope following an endoscopic retrograde cholangiopancreatography (ERCP) using a percutaneous gastrostomy access.

Efficacy and Safety of Digital Single-Operator Cholangioscopy for Difficult Biliary Stones Brewer Gutierrez O.I., Bekkali N.L.H., Rajman I., Sturgess R., Sejpal D.V., Aridi H.D., Sherman S., Shah R.J., Kwon R.S., Buxbaum J.L., Zulli C., Wassef W., Adler D.G., Kushnir V., Wang A.Y., Krishnan K., Kau V., Tzimas D., DiMaio C.J., Ho S., Petersen B., Moon J.H., Elmunzer B.J., Webster G.J.M., Chen Y.-I., Dwyer L.K., Inamdar S., Patrick V.B., Attwell A., Hosmer A., Ko C. aurano A., Sarkar A., Taylor L.J., Gregory M.H., Strand D.S., Raza A., Kothari S., Harris J.P., Kumta N.A., Manvar A., Topazian M.D., Lee Y.N., Spiceland C.M., Trindade A.J., Bukhari M.A., Sanaei O., Ngamruengphong S., Khashab M.A. *Clinical Gastroenterology and Hepatology* 2018 16:6 (918-926.e1)²⁰

Background & Aims:

It is not clear whether digital single-operator cholangioscopy (D-SOC) with electrohydraulic and laser lithotripsy is effective in removal of difficult biliary stones. We investigated the safety and efficacy of D-SOC with electrohydraulic and laser lithotripsy in an international, multicenter study of patients with difficult biliary stones.

Methods:

We performed a retrospective analysis of 407 patients (60.4% female; mean age, 64.2 years) who underwent D-SOC for difficult biliary stones at 22 tertiary centers in the United States, United Kingdom, or

Korea from February 2015 through December 2016; 306 patients underwent electrohydraulic lithotripsy and 101 (24.8%) underwent laser lithotripsy. Univariate and multivariable analyses were performed to identify factors associated with technical failure and the need for more than 1 D-SOC electrohydraulic or laser lithotripsy session to clear the bile duct.

Results:

The mean procedure time was longer in the electrohydraulic lithotripsy group (73.9 minutes) than in the laser lithotripsy group (49.9 minutes; $P < .001$). Ducts were completely cleared (technical success) in 97.3% of patients (96.7% of patients with electrohydraulic lithotripsy vs 99% patients with laser lithotripsy; $P = .31$). Ducts were cleared in a single session in 77.4% of patients (74.5% by electrohydraulic lithotripsy and 86.1% by laser lithotripsy; $P = .20$). Electrohydraulic or laser lithotripsy failed in 11 patients (2.7%); 8 patients were treated by surgery. Adverse events occurred in 3.7% patients and the stone was incompletely removed from 6.6% of patients. On multivariable analysis, difficult anatomy or cannulation (duodenal diverticula or altered anatomy) correlated with technical failure (odds ratio, 5.18; 95% confidence interval, 1.26–21.2; $P = .02$). Procedure time increased odds of more than 1 session of D-SOC electrohydraulic or laser lithotripsy (odds ratio, 1.02; 95% confidence interval, 1.01–1.03; $P < .001$).

Conclusions:

In a multicenter, international, retrospective analysis, we found D-SOC with electrohydraulic or laser lithotripsy to be effective and safe in more than 95% of patients with difficult biliary stones. Fewer than 5% of patients require additional treatment with surgery and/or extracorporeal shockwave lithotripsy to clear the duct.

[Apple Far from the Tree”: comparative effectiveness of fiberoptic single-operator cholangiopancreatography \(FSOCP\) and digital SOCP \(DSOCP\). Mizrahi M., Khoury T., Wang Y., Cohen J., Sheridan J., Chuttani R., Berzin T.M., Sawhney M.S., Pleskow D.K.. *HPB* 2018 20:3 \(285-288\)²¹](#)

Background:

While the fiberoptic single-operator cholangiopancreatography (FSOCP) system has demonstrated efficacy in the diagnosis and management of pancreaticobiliary diseases, the digital SOCP (DSOCP) appears to provide higher resolution digital imaging, however a comparison of these devices has not been established. The aim of this work was to compare the efficacy of FSOCP and DSOCP in biliary stone disease and indeterminate biliary strictures.

Methods:

A retrospective analysis of a prospective cohort was performed in patients undergoing FSOCP or DSOCP demographics included indication, diagnostic yield, procedure time, radiation dose, and complications.

Results:

324 patients underwent cholangioscopy. FSOCP and DSOCP were utilized in 198 and 126 patients respectively. Male/female ratio was similar and mean age was 66 ± 13 years. Indications included stone disease, indeterminate stricture evaluation and “other” were 47%, 42% and 11% respectively. Mean procedure time for stone disease and the amount of radiation doses in DSOCP group were lower than the FSOCP group ($P = 0.032$ and $P = 0.02$, respectively). Diagnostic yield in indeterminate strictures was higher 78% with DSOCP system compared to 37% with FSOCP system ($P = 0.004$). Complications were low and similar between the groups.

Conclusions:

DSOCP system provides enhanced diagnostic yield, shorter procedure times and less radiation exposure compared to FSOCP system

[Single-operator cholangiopancreatography in pancreaticobiliary diseases: Clinical experience in a tertiary referral hospital. Pons-Beltrán V., Alonso-Lázaro N., Mansilla-Vivar R., Sáez-González E., Ponce-Romero M., Argüello-Viudez L., Ramos-Soler D., Pérez-Rojas J., Leathers J., Bustamante-Balen M. *Revista Española de Enfermedades Digestivas* 2018 110:12 \(748-754\)²²](#)

Background and aims:

Assess the usefulness, efficacy and safety of single-operator cholangiopancreatography (SOCP) with the SpyGlass™ system for the management of biliopancreatic diseases.

Methods:

A retrospective analysis of patients undergoing SOCP with the SpyGlass™ between September 2008 and April 2016 was performed. Data was obtained from a prospectively- maintained database at a tertiary referral center. The primary study outcomes were technical and complete endoscopic success of the procedure. Two different Spy- Glass™ systems were employed; the former is called legacy and the latter, digital system (DS).

Results:

A total of 107 SOCP procedures in 93 patients performed by a single operator were analyzed. Technical success of the SpyGlass™ examination was achieved in 90/93 (97%) of patients and complete success by resolving the biliopancreatic condition in 82/93 (88%) cases. In indeterminate biliary strictures, a complete success was achieved in 45/52 (85%) of cases. With regard to stone treatment, technical success was achieved in 34/34 (100%) patients and complete success, in 31/34 (91%) cases. Electrohydraulic lithotripsy was applied in 16/34 (47%) of cases. There were a total of 7/93 adverse effects (7.5%).

Conclusions:

SOCP is a useful and safe technique for the treatment of biliopancreatic diseases with a low rate of adverse effects. The procedure seems technically demanding and dedication is required.

[Cholangioscopy in the digital era. Ayoub F., Yang D., Draganov P.V. *Translational Gastroenterology and Hepatology* 2018 3:October Article Number 82²³](#)

Cholangioscopy allows direct visualization and subsequent therapeutic maneuvers of the biliary ductal system. With advances in endoscopic and imaging technology, cholangioscopy has become an important modality for the diagnosis of indeterminate biliary strictures and an essential therapeutic tool for difficult to remove biliary stones. Enhanced imaging and operability of the latest generation cholangioscopes have further expanded their clinical applications to include ductal tumor ablation, gallbladder drainage, access to difficult to reach branches of the biliary tree, and biliary foreign body manipulation. In this review, we discuss the technical evolution of cholangioscopy into the digital era and review the clinical evidence supporting its use in the diagnosis and therapy of biliary tract disease.

[Single-operator cholangioscopy for biliary complications in liver transplant recipients Hüsing-Kabar A., Heinzow H.S., Schmidt H.H.-J., Stenger C., Gerth H.U., Pohlen M., Thölking G., Wilms C., Kabar I. *World Journal of Gastroenterology* 2017 23:22 \(4064-4071\)²⁴](#)

AIM:

To evaluate cholangioscopy in addition to endoscopic retrograde cholangiopancreatography (ERCP) for management of biliary complications after liver transplantation (LT).

METHODS:

Twenty-six LT recipients with duct-to-duct biliary reconstruction who underwent ERCP for suspected biliary complications between April and December 2016 at the university hospital of Muenster were consecutively enrolled in this observational study. After evaluating bile ducts using fluoroscopy, cholangioscopy using a modern digital single-operator cholangioscopy system (SpyGlass DS) was performed during the same procedure with patients under conscious sedation. All patients received peri-interventional antibiotic prophylaxis and bile was collected during the intervention for microbial analysis and for antibiotic susceptibility testing.

RESULTS:

Thirty-three biliary complications were found in a total of 22 patients, whereas four patients showed normal bile ducts. Anastomotic strictures were evident in 14 (53.8%) patients, non-anastomotic strictures in seven (26.9%), biliary cast in three (11.5%), and stones in six (23.1%). A benefit of cholangioscopy was seen in 12 (46.2%) patients. In four of them, cholangioscopy was crucial for selective guidewire placement prior to planned intervention. In six patients, biliary cast and/or stones failed to be diagnosed by ERCP and were only detectable through cholangioscopy. In one case, a bile duct ulcer due to fungal infection was diagnosed by cholangioscopy. In another case, signs of bile duct inflammation caused by acute cholangitis were evident. One patient developed post-interventional cholangitis. No further procedure-related complications occurred. Thirty-seven isolates were found in bile. Sixteen of these were gram-positive (43.2%), 12 (32.4%) were gram-negative bacteria, and *Candida* species accounted for 24.3% of all isolated microorganisms. Interestingly, only 48.6% of specimens were sensitive to prophylactic antibiotics.

CONCLUSION:

Single-operator cholangioscopy can provide important diagnostic information, helping endoscopists to plan and perform interventional procedures in LT-related biliary complications.

[A feasibility study of digital single-operator cholangioscopy for diagnostic and therapeutic procedure \(with videos\). Imanishi M., Ogura T., Kurisu Y., Onda S., Takagi W., Okuda A., Miyano A., Amano M., Nishioka N., Masuda D., Higuchi K. *Medicine \(United States\)* 2017 96:15 Article Number e6619²⁵](#)

Recently, the novel SpyGlass DS Direct Visualization system (SPY DS) has become available. This system offers several advantages over the conventional SPYGlass system. This study evaluated the clinical feasibility and efficacy of diagnostic and therapeutic procedures for biliary disorder using SPY DS. In this retrospective study, consecutive patients who had biliary disorder were enrolled between November 2015 and February 2016. All patients could not be diagnosed or treated by standard endoscopic retrograde cholangiopancreatography in our hospital or at another hospital. A total of 28 consecutive patients (21 men and 7 women; median age, 73 years; age range, 55-87 years) were retrospectively enrolled in this study. Among them, diagnostic procedure was performed in 20 patients, and 8 patients underwent therapeutic procedures. The technical success rate for diagnostic procedures was 100% (20/20). Diagnostic accuracy was 100% (19/19). The technical success rate for therapeutic procedures was 88% (7/8). Among these 8 patients, 4 patients with common bile duct stones underwent electrohydraulic lithotripsy. One patient successfully underwent guidewire insertion to remove a migrated plastic stent. The 3 remaining patients underwent SPY DS to insert a guidewire for left bile duct obstruction and for posterior bile duct branch. In the patient who underwent guidewire insertion for left hepatic bile duct obstruction cause by primary sclerosing cholangitis, we could not advance the guidewire into the left hepatic bile duct. No adverse events were seen. Median SPY DS insertion time was 21 min (range, 8-32 min). Single-operator cholangioscopy using SPY DS was feasible and had a marked clinical impact in patients with biliary disease. Additional case reports and prospective studies are needed to examine further applications of this system

[Efficacy and safety of novel digital single-operator peroral cholangioscopy-guided laser lithotripsy for complicated biliary stones. Wong J.C.T., Tang R.S.Y., Teoh A.Y.B., Sung J.J.Y., Lau J.Y.W. *Endoscopy International Open* 2017 5:1 \(E54-E58\) 26](#)

Background/study aims:

Laser lithotripsy can effectively fragment complicated biliary stones, but current cholangioscopes are limited by fragility, restricted mobility or moderate visual resolution. The efficacy and safety of a new digital single-operator peroral cholangioscope to guide laser lithotripsy were evaluated.

Patients and methods:

In this prospective single-center series, consecutive patients with complicated biliary stones, defined as impacted stones >1.5cm in size and wider than the more distal common bile duct, or stones that failed

extraction by basket mechanical lithotripsy, underwent ERCP and SpyGlass DS peroral cholangioscope (Boston Scientific, Marlborough, United States)-guided laser lithotripsy. Stone clearance rate and incidence of adverse events were determined.

Results:

Seventeen patients (10 men, 7 women; median age 76 years) with a median biliary stone size of 2cm underwent predominantly holmium yttrium aluminum garnet laser lithotripsy, achieving a 94% stone clearance rate over 1 median procedure. Lithotripsy was performed in 8 of 17 patients due to an impacted biliary stone. The remaining patients underwent lithotripsy due to prior failure of the basket mechanical lithotripter to capture or crush their stones. Post lithotripsy, 2 patients developed cholangitis and 1 patient with underlying COPD developed respiratory distress, all resolved with conservative management. There were no hemobilia, perforations, pancreatitis nor any deaths.

Conclusion:

SpyGlass DS peroral cholangioscopy-guided laser lithotripsy is an efficient and safe modality for management of complicated biliary stones.

El servicio solicitante nos aporta en su solicitud el siguiente documento:

[Role of digital single-operator cholangioscopy in the diagnosis and treatment of biliary disorders. World J Gastrointest Endosc 2019 January 16; 11\(1\): 31-40²⁷](#)

Due to the need for improvement in the diagnosis and minimally invasive therapy of the bile duct disorders new technologies for cholangioscopy have been recently developed. Per-oral cholangioscopy has become an important diagnostic and therapeutic tool leading to avoidance of aggressive and unnecessary surgery in many clinical scenarios. This paper focuses on the newly developed SpyGlass DS technology, its advantages, and the technique of single-operator cholangioscopy (SOC), biliary indications and possible adverse events. We also review the available literature; discuss the limitations and future expectations.

Digital SOC (D-SOC) is a useful technique, which provides endoscopic imaging of the biliary tree, optical diagnosis, biopsy under direct vision and therapeutic interventions. The implementations are diagnostic and therapeutic. Diagnostic indications are indeterminate biliary strictures, unclear filling defects, staging of cholangiocarcinoma, staging of ampullary tumors (extension into the common bile duct), unclear bile duct dilation, exploring cystic lesions of the biliary tree, unexplained hemobilia, posttransplant biliary complications. Therapeutic indications are lithotripsy of difficult stones, retrieval of migrated stents, foreign body removal, guide wire placement, transpapillary gallbladder drainage and endoscopic tumor ablative therapy. Most studied and established indications are the diagnosis of indeterminate biliary stricture and intraductal lithotripsy of difficult stones. The adverse events are not different and more common compared to those of Endoscopic retrograde cholangiopancreatography (ERCP) alone. D-SOC is a safe and effective procedure, adjunct to the standard ERCP and the newly available digital technology overcomes many of the limitations of the previous generations of cholangioscopes.

6. PRINCIPALES CONCLUSIONES Y RECOMENDACIONES DEL INFORME DE EVALUACIÓN

La perspectiva de visualizar el árbol biliopancreático ha seducido a los endoscopistas durante décadas. La combinación de la endoscopia y el enfoque radiográfico por medio de la colangiopancreatografía retrógrada endoscópica (CPRE) ha sido y sigue siendo la herramienta principal para intervención biliopancreática. Sin embargo tiene la desventaja de una visualización y aplicación de terapia indirecta por fluoroscopia.

Aunque la mayoría de los problemas clínicos y algunos tratamientos pueden ser resueltos con CPRE, existen situaciones difíciles y desafiantes como las estenosis biliares indeterminadas y las piedras difíciles en conductos, en las que la visualización directa del conducto biliar con la posibilidad de realizar biopsias y terapia asistida como la electrohidráulica sobre piedras difíciles, justifican el uso de esta nueva tecnología.

Los diferentes estudios que evalúan el papel del Spy Glass en la definición de estenosis biliares comparan los resultados con otras técnicas y demuestran un considerable incremento en el rendimiento diagnóstico, si bien, la interpretación de los hallazgos visuales colangioscópicas sigue siendo un desafío, y hasta la fecha, existe una falta de uniformidad y un escaso acuerdo entre observadores en la interpretación visual de los mismos. La evaluación visual debe combinarse siempre con una guía óptica de biopsias. Después de todo, excepto por la neoangiogénesis, no hay características macroscópicas distintivas o reconocimiento de patrones para descartar la naturaleza benigna o maligna de una lesión.

Un campo de desarrollo actual es el establecimiento de criterios visuales refinados para la distinción de lesiones benignas/malignas y la mejora adicional de las pinzas de biopsia y del protocolo de biopsia. Actualmente, un ensayo clínico²⁸ que está en marcha comparará el DSOC primario (SpyGlass) con la CPRE en pacientes con estenosis biliar indeterminada. El SpyGlass ayuda a proporcionar el diagnóstico visual de las estenosis basado en patrones morfológicos y vasculares, además de una biopsia intraductal dirigida (SpyBite) de las lesiones. La combinación de ambos métodos debería aumentar el rendimiento diagnóstico en la evaluación de la estenosis biliar indeterminada por DSOC. Debido a sus altos costes, el DSOC se ofrece principalmente más tarde, es decir, cuando la citología de la CRPE fracasó (DSOC secundario). Este tiempo perdido puede ser importante y determinante para el resultado de los pacientes. Por lo tanto, la colangioscopia primaria podría ayudar en el tratamiento correcto de pacientes con estenosis biliar indeterminada, sin pérdida de tiempo. Además, la creación de un banco de imágenes y establecer una clasificación macroscópica de las lesiones podría ayudar a distinguir las lesiones benignas de las malignas con una buena concordancia.

Los pacientes que se someten a esta técnica por definición son más complejos, aumentando el riesgo de complicaciones. Los eventos adversos son mayores que por la realización aislada de CPRE, aunque asumibles. Los más frecuentes son la colangitis, pancreatitis y hemorragia. Oscilan entre un 5% y el 13%.

El riesgo de colangitis podría considerarse más probable en pacientes con cálculos y estenosis donde la retención de líquidos es más frecuente. Este riesgo podría ser controlado por el uso de antibióticos profilácticos, práctica habitual cuando se usa el Spy Glass. La hemobilia es otra complicación específica de este dispositivo, que debemos considerar con la litotricia y resulta de la aplicación no intencional del contacto de la sonda con la pared del conducto biliar.

La principal limitación del método es el coste del procedimiento. La colangioscopia con el sistema SpyGlass DS es un procedimiento costoso debido al alto precio del procesador y debido a que el SpyScope y todos los demás dispositivos son totalmente desechables. Sería necesario realizar un estudio económico que eche luz en el coste efectividad de esta tecnología.

Derdeyn¹⁶ et al, realizaron un análisis del impacto económico de SpyGlass tanto para el escenario de las estenosis indeterminadas como para el tratamiento de las piedras difíciles en los conductos biliares, usando el conjunto de datos de dos hospitales universitarios belgas con experiencia con este procedimiento. Para el análisis económico, se adoptó una perspectiva hospitalaria utilizando un enfoque de micro-costing, es decir, multiplicando el número de recursos directamente utilizados durante el procedimiento por el coste unitario de los mismos, combinados con los costes de hospitalización. El

estudio mostró que el uso del Sistema Digital SpyGlass fue rentable para estos dos procedimientos. La adopción de SpyGlass Sistema digital para la gestión de piedras difíciles permite evitar alrededor del 27% de los procedimientos y ahorra alrededor del 11% del presupuesto asignado. De manera similar, la adopción del Sistema Digital SpyGlass para el diagnóstico de estenosis permite evitar alrededor del 31% de los procedimientos y una reducción del 5% de los costes. La colangioscopia SpyGlass DS puede ser más rentable en comparación con la CPRE sola, dependiendo de los criterios de selección según reflejan en su estudio. Además el valor predictivo negativo absoluto de la impresión visual proporcionó seguridad a los pacientes con estenosis benignas que evitaron la cirugía innecesaria en un 53%¹⁵ con el consiguiente ahorro.

Otra limitación son los conocimientos requeridos y formación de endoscopistas experimentados ya que la técnica a pesar de ser muy alentadora sobre su utilidad, precisa de una alta experiencia en CPRE, y se requiere una estricta selección de los pacientes. A día de hoy no existe una recomendación formal del número mínimo de casos a tratar para adquirir competencia en su manejo, estimándose una curva de aprendizaje menor respecto a otras técnicas endoscópicas que precisan tutelaje. La casa comercial solo refleja la recomendación de tener experiencia avanzada en CPRE antes de iniciarse en esta técnica.

Los beneficios potenciales pueden ser múltiples: evita cirugías, evita en ocasiones la radioscopia (menor radiación para pacientes y personal y disponibilidad del técnico y equipo de rayos para otra tarea), la rapidez del procedimiento, menor número de sesiones endoscópicas, estancias hospitalarias más cortas y costes más bajos disminuyendo el consumo de recursos (salas, anestesistas, etc).

7. CONSIDERACIONES PARA NUESTRA COMUNIDAD

En la actualidad existen endoscopistas que realizan técnicas similares que podrían estar facultados para llevar a cabo esta técnica. Sin embargo, parece prudente que antes de ejecutarla realicen un periodo de entrenamiento habitualmente facilitado por la casa comercial.

La realidad es que el sistema de visualización directa permite acceso endoscópico a las vías biliares y pancreáticas posibilitando la obtención de biopsias además de procedimientos terapéuticos como la litotricia de grandes litiasis o radiofrecuencia de tumores de vía biliar que hasta la fecha no era posible mediante la CPRE convencional.

Se estima el uso del dispositivo en aproximadamente un 5% de las CPRE que se realizan en el Hospital Universitario Central de Asturias (datos de CPRE anuales de últimos años: 363, 317,334 y 304), siendo unos 15-20 casos anuales.

Respecto a la adquisición de los dispositivos se podrían valorar diferentes opciones. Una opción facilitada por la casa comercial puede ser el renting del dispositivo litotricor, según previsión de uso, costes de adquisición y mantenimiento.

La implantación de esta nueva tecnología debería realizarse en centros de referencia con un protocolo clínico con indicaciones bien definidas y definiendo indicadores que posibiliten el seguimiento de los casos.

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