Cholangioscopy: Has It Changed Management?

Sudipta Dhar Chowdhury1  Rajeeb Jaleel1

1 Department of Gastroenterology, Christian Medical College, Vellore, India

Abstract

The single operator per oral cholangioscope is a catheter-based system that allows for direct visualization of the bile duct and pancreatic duct. The instrument with its improved imaging technique and larger accessory channel allows for high-quality image acquisition and performance of therapeutic and diagnostic procedures within the bile duct and pancreatic duct. There has been an increase in the range of indications for the use of the cholangioscope. The current indications include management of difficult biliary stones, pancreatic calculi, assessment of indeterminate biliary stricture, pancreatic stricture, intra-ductal papillary mucinous neoplasms, and extractions of proximally migrated stents. The use of laser lithotripsy and electro-hydraulic lithotripsy has improved the management of difficult bile duct stones. Direct visualization of biliary and pancreatic duct strictures is helpful in the diagnosis of indeterminate strictures. In this review, we explore how cholangioscopy has changed management.

Keywords
► bile duct
► biliary stricture
► cholangioscopy
► choleodocholithiasis
► pancreatoscopy
► spyglass

Introduction

Direct visualization of the biliary tree has been an area of active interest over the past century. Almost 100 years ago, J. Bakes, a Czechoslovakian surgeon described the use of a modified ear speculum with a light source and mirror for examination of the bile duct at surgery.1 However, it was only after McIver developed a rigid right-angled choledochoscope that cholangioscopy gained popularity.2 A flexible choledochoscope with a channel for irrigation and instrumentation was introduced by Shore et al.3 The improvement in instrumentation allowed for the use of cholangioscope per-cutaneously. However, it was only after the advent of the mother–baby scope in 1976 that cholangioscopy became an important part of an endoscopist’s therapeutic armamentarium.4 The mother–baby system consisted of a duodenoscope (the mother) through which a flexible cholangioscope (the baby) could be inserted. The mother–baby cholangioscope went out of favor as the system was fragile, had limited steerability, and the procedure required two endoscopists. With the development of the single operator per-oral cholangioscope system, (SpyGlass, Boston Scientific, Marlborough, MA, USA) cholangioscopy has regained popularity amongst the endoscopists and the areas of its use are gradually increasing.

Single Operator per Oral Cholangioscope: (SpyGlass, Boston Scientific)

This is a catheter-based system that can be operated by a single operator and allows direct visualization of the biliary system and the pancreatic ducts. The first-generation catheter-based single operator per oral cholangioscope the SpyGlass Direct Visualization system also known as the SpyGlass Legacy system was launched in 2007. The first generation SpyGlass cholangioscope was a very popular device and brought cholangioscopy to the main stream. However, it had a few limitations viz. the image quality was sub-optimal,
the field of view was limited, and it required a complicated setup. In 2015, the SpyGlass DS system was launched. The SpyGlass DS has a simplified “plug and play” setup. It has two parts: a processor (SpyGlass DS digital controller) and a disposable cholangioscope (Spy Scope DS catheter). The processor can be fitted on any standard endoscopy cart and has automatic white balance and focus. The Spy Scope DS catheter includes the handle, a connection cable for attaching the cholangioscope to the processor, and an insertion tube. The instrument is set up by attaching the connection cable to the processor. The catheter handle is then attached to a standard duodenoscope and the insertion tube advanced through the working channel of the duodenoscope. The insertion tube includes one accessory channel (1.2 mm), two irrigation channels, and two optical fibers to transmit light from the processor for illumination. The catheter is fitted with a digital camera at the tip, which provides a four times higher resolution and a 60% wider field of view than the first generation SpyGlass System (Table 1). In 2018, the third-generation Spy Scope DS II catheter was launched. In this system, the image resolution was improved further by incorporating a new CMOS chip and adjusted lighting, which reduces light flare and provides better down lumen visibility.

Cholangioscopy is performed with the duodenoscope positioned at the papilla, the cholangioscope is advanced across the papilla into the bile duct or pancreatic duct. A sphincterotomy or sphincteroplasty is usually performed before insertion of the cholangioscope to improve the ease of scope insertion.

In this review, we will discuss how cholangioscopy has changed the management of patients with biliopancreatic disorders. For this review “cholangioscope” and “pancreatoscope” refers to the single operator per-oral cholangioscopy (SpyGlass System).

### Indications for Cholangioscopy

The indications for cholangio-pancreatoscopy are increasing. Currently, the most frequent use of cholangioscopy is in the management of difficult bile duct stones and the evaluation of indeterminate biliary strictures (Table 2).

#### Difficult Bile Duct Stones

Stones within the biliary tree are a commonly encountered problem and 90% of the stones can be extracted using standard techniques. i.e., using a stone extraction balloon, or a stone extraction basket. However, there can be occasional challenges that make stone extraction using standard techniques difficult. These can be largely grouped into stone characteristics, stone location, and anatomy (Table 3). For stones larger than 15 mm endoscopic papillary dilatation in combination with endoscopic sphincterotomy can facilitate the extraction of stones. However, in situations where the stone size is larger than the bile duct (stone to bile duct ratio > 1.0), the stone is > 20 mm in diameter, the stone is above a stricture, or there is an acute angle of the distal common bile duct (CBD), it is necessary to fragment the stone within the biliary tree before extraction. Shock wave lithotripsy utilizes shock waves to fragment the stones and this can be applied extracorporeal (extracorporeal shock wave lithotripsy [ESWL]) or within the bile duct.

<table>
<thead>
<tr>
<th>Model</th>
<th>Usage</th>
<th>Catheter diameter (mm)</th>
<th>Accessory Channel diameter (mm)</th>
<th>Tip angulation</th>
<th>Scope length (mm)</th>
<th>Image</th>
<th>Field of view (degree)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spy GlassDirect Visualization System</td>
<td>Cholangioscope Catheter: single use Optical probe: reusable</td>
<td>3.4</td>
<td>1.2</td>
<td>30°/30°/30°/30°</td>
<td>2,300</td>
<td>Fiber optic</td>
<td>70</td>
</tr>
<tr>
<td>Spy Glass DS System</td>
<td>Cholangioscope : single use</td>
<td>3.56</td>
<td>1.2</td>
<td>60°/60°/60°/60°</td>
<td>2,140</td>
<td>Digital</td>
<td>120</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Table 1 Single operator per oral cholangioscope systems (SpyGlassDirect Visualization System and SpyGlass DS system)</th>
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<tbody>
<tr>
<td><strong>Biliary</strong></td>
</tr>
<tr>
<td>Difficult biliary stricture</td>
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<tr>
<td>Indeterminate biliary stricture</td>
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<tr>
<td>Extraction of migrated stents</td>
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<table>
<thead>
<tr>
<th>Table 2 Current indications of cholangio-pancreatoscopy</th>
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<tbody>
<tr>
<td><strong>Biliary</strong></td>
</tr>
<tr>
<td>Difficult biliary strictures</td>
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</tr>
<tr>
<td>Extraction of migrated stents</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3 Difficult bile duct stones</th>
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</thead>
<tbody>
<tr>
<td><strong>Difficulty level</strong></td>
</tr>
<tr>
<td>a) Large stone ≥ 15 mm</td>
</tr>
<tr>
<td>c) Barrel-shaped stones</td>
</tr>
<tr>
<td><strong>Stone location</strong></td>
</tr>
<tr>
<td>a) Intrahepatic stones</td>
</tr>
<tr>
<td>b) Stones above a stricture</td>
</tr>
<tr>
<td>c) Mirrizi’s syndrome</td>
</tr>
<tr>
<td>d) Acute angle of distal CBD ≤ 135 degrees</td>
</tr>
</tbody>
</table>
Cholangioscopy allows for endoscopic access to the bile duct for direct visualization and fragmentation of stones. Cholangioscopy, assisted stone extraction is usually performed by utilizing shock waves delivered using laser lithotripsy or electrohydraulic lithotripsy.

**Laser Lithotripsy**

Laser light is monochromatic (i.e., of one wavelength), directional and coherent. These properties of laser light allow for its application in medical procedures. Pulsed solid-state lasers (holmium: YAG) are used for lithotripsy. Pulsed lasers can generate very high power for very short periods and therefore decrease the risk of injury. Laser light creates a plasma (collection of electrons and ions) at the surface of the stone and adjacent fluid. Expansion of the plasma creates a high-energy shock wave that fractures the stone (Video 1). Laser machines allow for the modulation of pulse energy (Joule) and pulse frequency (Hertz) and thereby the power (Watt) of the laser machine, which is a product of energy (J) and frequency (Hz). The laser fibers are usually 4 m long and vary in diameter (200, 365, 550, or 1000 micrometre). The commonly used fiber diameter is 365 micro M. Laser lithotripsy (LL) has been compared with conventional therapy (mechanical lithotripsy, EPLBD) and surgery. With LL, successful stone clearance can be achieved in > 90% of patients (Table 4).

**Electrohydraulic Lithotripsy**

The electrohydraulic lithotripsy (EHL) probe is a bipolar probe that is connected to a charge generator. With the probe tip positioned 1 to 2 mm from the surface of the stone, the application of charge to the bipolar probe in short pulses creates sparks that induce expansion and contraction of surrounding fluid resulting in an oscillatory shock wave. This shock wave fragments the stone. Continuous saline irrigation is required during EHL for shock wave

### Table 4 Randomized controlled trial comparing laser with conventional techniques

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Study design</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Number (ratio)</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Li et al, 2021</td>
<td>RCT; Non inferiority</td>
<td>Large CBD stone ( \geq 2 ) cm</td>
<td>LL</td>
<td>LCBDE</td>
<td>157 (1:1)</td>
<td>LL not inferior. First session clearance lower in LL</td>
</tr>
<tr>
<td>Bang et al, 2020</td>
<td>RCT</td>
<td>Difficult bile duct stones – failed retrieval with balloon or basket</td>
<td>LL</td>
<td>LBS</td>
<td>66 (1:1)</td>
<td>Laser: 93.9. LBS: 72.7 ( p = 0.021 )</td>
</tr>
<tr>
<td>Angsuwatcharakon et al, 2019</td>
<td>RCT</td>
<td>Large bile duct stones that were either not amenable/failed EPLBD</td>
<td>LL</td>
<td>Mechanical lithotripsy</td>
<td>32 (1:1)</td>
<td>Stone clearance 100% vs 63% ( p &lt; 0.01 ) (favoring laser lithotripsy)</td>
</tr>
<tr>
<td>Buxbaum et al, 2018</td>
<td>RCT</td>
<td>Patients with bile duct stones &gt;1 cm in diameter</td>
<td>LL</td>
<td>Conventional (mechanical lithotripsy and EPLBD)</td>
<td>60 (2:1)</td>
<td>Laser: 93, Conventional: 67% ( p = 0.009 )</td>
</tr>
</tbody>
</table>

**Abbreviations:** EPLBD, endoscopic papillary large balloon dilatation; LBS, large balloon sphincteroplasty; LCBDE, laparoscopic common bile duct exploration; LL, laser lithotripsy.

### Table 5 Electrohydraulic lithotripsy (EHL) for biliary stones

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study design</th>
<th>Population</th>
<th>Intervention</th>
<th>Number</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Binmoller et al, 1992</td>
<td>Prospective observational study</td>
<td>Patients with extrahepatic stones</td>
<td>EHL</td>
<td>108 difficult stones: EHL done in 65</td>
<td>Stone clearance in 64 (98.5%)</td>
</tr>
<tr>
<td>Kamiyama et al, 2018</td>
<td>Retrospective study</td>
<td>Difficult bile duct stone</td>
<td>Cholangioscope assisted: 34 Percutaneous: 8</td>
<td>42</td>
<td>Stone clearance 41 (98%)</td>
</tr>
<tr>
<td>Minami et al, 2021</td>
<td>Observational study</td>
<td>Difficult biliary stone (intrahepatic, CBD and CD)</td>
<td>Cholangioscope assisted</td>
<td>EHL-88 LL-2</td>
<td>Complete stone removal (92.2%)</td>
</tr>
</tbody>
</table>

**Abbreviations:** CBD, common bile duct; CD, cystic duct.
transmission. EHL has been in use for lithotripsy for last couple of decades. More than 90% of the stones can be successfully cleared with EHL (Table 5). In a meta-analysis of 32 studies in which LL was compared with EHL, LL was found to have a higher rate of stone clearance (95.1% vs. 88.4%). Post-procedural complications appeared to be lower and the overall success rate was higher for LL (95.1% vs. 85.6%).

Pancreatic Calculi
Calcifications are a frequent finding in patients with chronic pancreatitis. Intraductal lithotripsy has been explored as a means of treating calculi within the main pancreatic duct. In a meta-analysis of 15 studies including 370 patients, 237 EHL and 136 LL procedures were performed. The clinical success for EHL was 91.6% and that for LL was 86.6%. Adverse events occurred in 12% of the patients who underwent LL compared with EHL (8.4% vs. 13.8%).

Indeterminate Biliary Stricture
Biliary stricture is considered indeterminate when basic work-up, transabdominal imaging, and ERCP with cytologic brushing are non-diagnostic. Cholangioscopy by its ability to directly visualize the biliary ducts offers a distinct advantage of visualizing the stricture and obtaining a tissue sample from the stricture under vision (Fig. 1). Macroscopic features that suggest that the stricture may be neoplastic include, tortuous dilated vessel, papillary projections, vegetative mass, irregular papillary or granular lesions, ulceration, friability, and easy bleeding. Several attempts have been made to classify lesions as neoplastic and non-neoplastic based on macroscopic features. Robles-Medranda et al made the first attempt at developing a classification for biliary lesions. Lesions with irregular or spider vascularity, irregular ulcerations, infiltrative patterns, or honeycomb patterns were classified as neoplastic. The Monaco classification is a recent attempt at developing a consensus definition for visual interpretation of the biliary stricture. Amongst the visual anomalies observed in a stricture the presence of ulceration and papillary projections were found to be highly associated with a diagnosis of malignancy. El Bacha et al identified three features that were diagnostic of malignant lesion viz. villous pattern, irregular vessels, and reddish aspect. The Mendoza classification is another consensus-based classification system aimed at macroscopic identification of neoplastic lesions. Three criteria viz. friability, tortuous dilated vessels, and raised intra-ductal lesions had the highest intraobserver agreement. In a meta-analyses of six studies, the pooled sensitivity, specificity, and diagnostic odds ratio for visual interpretation of indeterminate biliary stricture at cholangioscopy was 94% (95% confidence interval [CI]: 89–97), 95% (95%CI: 90–98), and 308.83 (95%CI: 106.46–872.82), respectively. In addition to visualization of the lesion, the cholangioscopes also allow for obtaining biopsy specimens from the stricture. In a meta-analysis of 11 studies that included 356 patients, the pooled sensitivity, pooled specificity, and odds ratio for visually directed biopsy in indeterminate biliary stricture was 0.74 (95% CI: 0.67–0.80), 0.98 (95% CI: 0.95–1.00), and 65.18 (95% CI: 26.79–158.61), respectively. The overall sensitivity of cholangioscope assisted biopsy appears to be lower than the visual impression. This could be possibly related to lax criteria used for macroscopic identification of neoplastic lesion and the poor quality of tissue obtained at cholangioscopy with the older generation SpyBite forceps. Recently, the SpyBite Max biopsy forceps has been introduced. In this forceps, the internal spike has been removed and the cups have front and side serrated teeth profile along with two long fenestrated holes to allow grasp of a larger tissue sample. The change in the design of the forceps will probably help improve the sensitivity of cholangioscope-assisted tissue acquisition.

Lesions in Pancreatic Duct
The utility of the cholangioscope is now being explored for the management of lesions in the pancreatic duct (pancreatoscopy). Pancreatic duct strictures and dilatations can occasionally pose diagnostic challenges for clinicians. A 13-year study from the United States explored the role of per oral pancreatoscope in differentiating malignant and benign lesions of the pancreatic duct. A total of 102 pancreatoscopy procedures were done in 79 patients. The sensitivity of detecting a neoplastic lesion based on visual impression was 87% and this improved to 91% with the addition of biopsy under direct vision. Adverse events that were predominantly in the form of post-procedural abdominal pain were reported in 12% of the patients. Pancreatoscopy has also been found to be of help in intra-ductal papillary mucinous neoplasms (IPMN). Using a mother–baby system, Hara et al classified the findings in patients with IPMN into five groups, viz. granular type, fish-egg-like type without vascular images, fish egg-like type with vascular images, villous type, and vegetative type. In a retrospective multicenter study of patients with main duct IPMN, 42% of patients had findings at pancreatoscopy that were not seen on cross-sectional imaging. Pancreatoscopy dictated the type of surgery in 77% of patients with diffusely dilated main pancreatic duct (> 10 mm). The authors concluded that pancreatoscopy should be included in the diagnostic algorithm of main duct IPMN in patients with a dilated main pancreatic duct.

Extraction of Migrated Stents
Plastic stents are commonly deployed in both pancreatic and biliary ducts. Stents at both these locations have a risk of
Recently, SpyGlass Retrieval snare with a snare diameter of has been shown to improve stent patency and overall sur-

quency ablation (RFA) of unresectable cholangiocarcinomas 
extraction baskets, Soehendra’s migrated stents including rat tooth forceps, snares, stone 
ments have been described to extracted the proximally 

grated pancreatic stents, by holding the stent tip (our center, we have successfully used the SpyBite forceps 

especially in proximally migrated pancreatic duct stents. In 

major papilla. (Fig. 2). 

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pre-procedure and post-procedure evaluation of the tumor after application of RFA. With improvement in the present 

accessories such as a larger cup of the SpyBite forceps and durable baskets and snares the range of therapeutic appli-

ations of cholangioscope is set to widen.

Conflict of Interest 
None declared.

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for difficult bile duct stones under endoscopic retrograde chole-
angiopancreatography and peroral transluminal cholangioscopy 

cholangioscopy-guided procedures for the diagnosis of bili-
ary strictures and treatment of difficult bile duct stones: a

Fig. 2 (A) MRCP: Dilated main pancreatic duct with proximally 
migrated stent within the MPD. (B) Pancreatoscropy: The stent tip is 
held by SpyBite forceps and extracted from the MPD through the 

major papilla. (C) Extracted plastic stent.

proximal and distal migration. Distally migrated stents can 
produce bowel obstruction, perforation, or recurrent choll-
gangitis. Proximal migration of stents can result in biliary 
pain, cholangitis, formation of stricture or stone around the 

stent. The risk of proximal stent migration for both biliary 
and pancreatic stent is ~5%. Several techniques and instru-
ments have been described to extracted the proximally 
migrated stents including rat tooth forceps, snares, stone 

extraction baskets, Soehendra’s stent extraction device. However, at times the above techniques are not successful 
especially in proximally migrated pancreatic duct stents. In 

our center, we have successfully used the SpyBite forceps 
with SpyGlass system for the extraction of proximally mi-
grated pancreatic stents, by holding the stent tip (Fig. 2). 

Recently, SpyGlass Retrieval snare with a snare diameter of 
9 mm has been introduced for the extraction of stents.

Future Directions

In this review, we have attempted to present the current 
aplications of cholangioscope and how it has changed 
management. In the near future, we foresee a wider range of 
aplications. With better image processing and maneu-
erverability, the need for fluoroscopy will probably diminish. A 
recent development in the visual interpretation of indeter-
minate stricture visualized at cholangioscopy is the intro-
duction of artificial intelligence. Mascharenas et al developed 
a deep learning algorithm that can accurately differentiate 
malignant from non-malignant biliary stricture. Radiofre-
cy-ablation (RFA) of unresectable cholangiocarcinomas 
has been shown to improve stent patency and overall sur-

vival. There is an emerging role of cholangioscopes in the