

Cholangiopancreatography. Working protocol. SEED recommendations

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ABSTRACT

Direct endoscopic visualization of biliary and pancreatic ducts represents one step further in the journey of digestive endoscopy. It allows the identification of lesions that were previously attainable through indirect means. Directed biopsy taking has permitted a better characterization of the lesions. The use of power sources through the cholangiopancreatograph means that it is now possible to fragment and remove refractory lithiasis using traditional endoscopic systems. This document aims to define the advisable workflow when using a single-use, flexible cholangiopancreatograph with the commercial name of SpyGlass®. Penning a set of guidelines to provide instructions on the technique, as well as tips and tricks related with the operation of these endoscopes will be a useful resource.

Keywords: Cholangioscopy. Pancreatography. Electrohydraulic lithotripsy. Laser lithotripsy.

INTRODUCTION

Direct endoscopic visualization of the bile ducts and pancreatic ducts represents a step further in the journey of digestive endoscopy. It allows the identification of lesions that were previously detected by indirect means. Directed biopsy taking has permitted a better characterization of lesions. The use of power sources through a cholangiopancreatograph means that it is now possible to fragment and remove refractory gallstones with traditional endoscopic techniques.

The present document aims to define the workflow recommended by the Spanish Society of Gastrointestinal Endoscopy (SEED) when using a single-use, flexible cholangiopancreatograph (SpyGlass®, Boston Scientific). The two

digital versions of the device, SpyScope DS and DS II, have incorporated technological improvements.

This working protocol offers a review by a team of SEED experts and discusses in depth the practical aspects of the endoscopic technique. Performing a flexible cholangiopancreatography (FCP) procedure through a duodenoscope requires, according to each phase of the technique, a coordinated, multidisciplinary effort involving an endoscopist, nurse, anesthesiologist and radiology technician.

DUODENOSCOPIC WORK PHASE

A number of recommendations are established:

- *Patient positioning.* Habitual options include the left lateral and prone positions. The prone position allows a greater stability of the duodenoscope and better radiographic images. However, airway access and control may be compromised in the prone position, particularly in short-necked obese patients with grades III and IV of the Mallampati's classification. While the supine position facilitates radiographic anatomy visualization, it also increases the risk for bronchoaspiration.
- *CO₂ insufflation* is recommended.
- Performing *papillotomy/sphincterotomy* with case-appropriate extent and/or elasticity allows the passage of a cholangiopancreatograph. A shorter

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papillotomy reduces air migration into the biliary tract (BT) and better retains instilled saline. In the case of intraductal lithotripsy, a wider sphincterotomy or a sphincteroplasty is helpful in order to facilitate fragment removal.

- Achieving maximal *duodenoscope stability*. The short route should be the first choice. The long route would be an alternative.
- Should duodenoscope instability occur, an *assistant* or second endoscopist might be required to hold it in place or stabilize it.
- Obtaining an *access axis and angle* favoring FCP insertion into the biliary tract is desirable. The more acute the angle at the duodenoscope's distal end, the more difficult FCP progression and instrument passage through the work channel will be (Fig. 1).

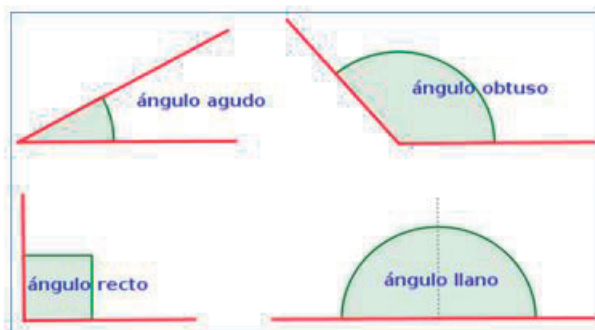
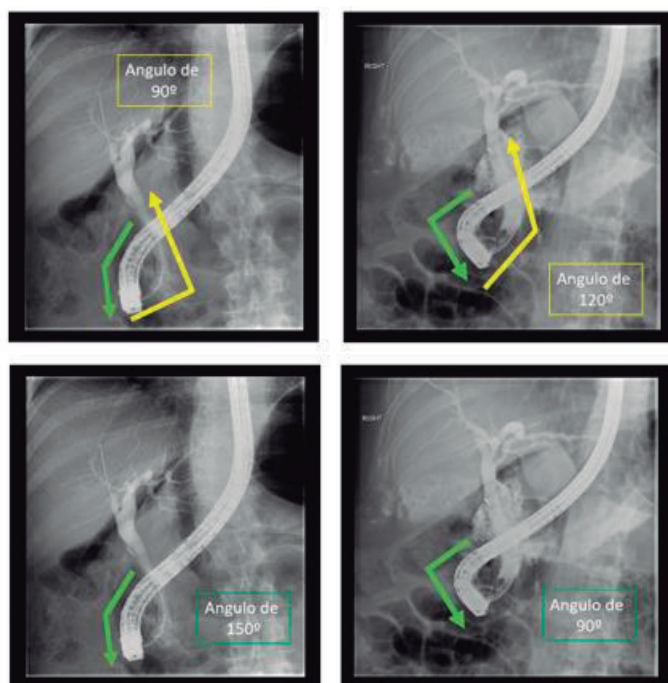


Fig. 1. Angles of curvature of the flexed duodenoscope tip (green arrow) and of the longitudinal axis of the biliary tract (yellow arrow), and ease of cholangioscope progression. The more obtuse the angle of curvature of the flexed duodenoscope tip and the longitudinal axis of the biliary tract, the greater the ease of cholangioscope progression. Radiographic images must be used to obtain this information. The angle of the longitudinal axis of the biliary tract may be modified by slightly advancing the duodenoscope in the caudal direction.

Obtuse or straight angles should be favored, as they offer a much easier progression.

- *Rectifying duodenoscope angles* at its flexion curvature and alignment with the longitudinal axis of the BT are advisable during FCP progression. Radiographic images are very helpful when performing these maneuvers (1,2) (Fig. 1).

RADIOGRAPHIC WORK PHASE

The following factors should be taken into account:

- *Injection of water-soluble radiographic contrast* should be adjusted to the purported purpose. The minimum volume needed to obtain the desired information should be used and adapted to BT dimensions. Previously delimited lesions may require minimal injections.
- *Contrast viscosity is high*, which results in a greater friction for the accessories passed through the working channel, and reduces cholangioscopic image sharpness. Sufficient aspiration should improve sharpness.
- *Diluting radiographic contrast* by 50 % with saline is recommended, as it may facilitate aspiration.
- *Contrast leakage through the sphincterotomy* should be considered. Procedures should be ordered as follows: first cholangiography with identification of the target lesion, then sphincterotomy.
- *Contrast overlay* with the gallbladder, cystic duct or main pancreatic duct may occur. Inclination maneuvers of the x-ray gantry and oscillation of the operating table in the Trendelenburg position may improve visualization of the target lesion.
- Lesion location improves by *combining cholangioscopic and radiographic images*.
- Keeping a radiographic image, including the target lesion, in a second monitor will help preserve topographic landmarks during cholangioscopy and reduce exposure to x-rays (3,4).

CHOLANGIOSCOPIC WORK PHASE

- It is recommended that all ports of the SpyGlass® and the duodenoscope's working channel be *flushed out with saline solution*.
- Aligning duodenoscope controls with cholangioscope controls is recommended (Fig. 2).
- Placement of monitor *screens at an ergonomic position*. Having a dual image on the screen using the so-called PIP (picture in picture) mode is advisable. In this way, both the cholangioscopic and duodenoscopic images are displayed on the same monitor.
- The introduction of the SpyGlass® through the duodenoscope's work channel should proceed in *short progression steps* (1-2 cm), with care to avoid crimping. This is also valid for all accessories inserted into the work channel.
- Progression of the SpyGlass® is easier and smoother with a *stabilized, rectified duodenoscope*. That is, approaching the duodenal papilla via the short route, with minor acute angles. During the cholangioscope introduction process, the elevator should



Fig. 2. Alignment of the duodenoscope and cholangioscope controls. Image courtesy of Boston Scientific.

be kept lowered. Resistance to advance of the scope will indicate that the duodenoscope's distal end has been reached.

- *Lubrication* with saline and liquid or spray silicone of the guidewire and instruments before insertion in the cholangioscope will facilitate lodging and shorten exchange time.
- *SpyGlass® progression over a guidewire* will ensure safety. Without a guidewire, cholangioscope progression may increase the risk of damaging the BT (5).
- From this moment on, the introduction of the SpyGlass® into the main biliary tract must ensue with *shorter pushes*, with a sequence of openings and closings of the elevator bridge, similar to that performed when introducing a plastic biliary stent.
- Small corrections should be applied to the axis of the duodenoscope. Supplementary radiographic views may be of help.
- The *guidewire may be withdrawn upon cannulation completion or once the target lesion has been reached*. This allows contrast and debris aspiration, facilitates irrigation with saline, and eases rigidity. The presence of a guidewire limits movement at the cholangioscope's distal end. The guidewire may be reused for selective cannulation of strictures or intrahepatic ducts.
- The *Y-port adapted to the work channel* of the cholangioscope has a screw cap to open or close the entrance to the working channel, which facilitates the passage of a guidewire, forceps, basket, snare or lithotripsy probe. Locks are useful during lithotripsy. This valve offers the possibility of locking without

blocking, maintaining some aspiration capacity for bile duct contents.

- *Antibiotic prophylaxis* is recommended. In some patients, particularly those with a stricture, incomplete drainage of an injected duct or immunocompromised, antibiotics, for example ciprofloxacin, may be given for 5-7 days (6).
- As *prophylaxis of acute pancreatitis* post-cholangiopancreatography, adherence to the recommendations by the European Society of Gastrointestinal Endoscopy (ESGE) is advised: diclofenac or indomethacin 100 mg via the rectal route, immediately before or after endoscopic retrograde cholangiopancreatography (ERCP), for all patients without contraindication for non-steroidal anti-inflammatory drugs, hydration with Ringer's lactate solution and a pancreatic stent as needed (6-8).

Radiographic contrast aspiration

The aspiration of previously injected radiographic contrast will allow a higher-quality view. The recommendations are as follows:

- Aspiration from the Y-port after guidewire removal and closure.
- Aspiration may be performed using 10-20 cc syringes.
- A *recommendable alternative* for radiographic contrast aspiration is doing it before the cholangioscope is passed. That is, following injection aspirate through the same sphincterotome under radiographic control to achieve a rapid, complete removal of the contrast medium.
- Subsequent contrast instillations may be necessary (5,9).

Biliary tract distension

- It is preferable to *progress towards proximal choledochal segments* while aspirating contrast, bile and debris.
- *Purge filling systems*. The presence of air bubbles impairs cholangioscopic visualization.
- *Initiate instillation with saline solution* on withdrawal (from intrahepatic duct bifurcation towards the distal common bile duct) to improve visualization. The instilled volume should be in direct relation to *BT diameter*.
- Use only *the saline volume needed* for good visualization. Enough has been instilled when saline is seen starting to flow through the sphincterotomy.
- Filling-aspiration devices with a *three-way valve* are faster and provide a smoother operation. Infusion pumps may also be used under the control of the operator using a pedal.
- By instilling saline solution, an *underwater view* is obtained, which may be particularly useful for interpreting villous components in some lesions (5,9).

Progression and biliary tract examination

- It is advisable to *patiently examine the mucosal surface of bile ducts on withdrawal* of the cholangioscope.

- For selective cannulation of an intrahepatic bile duct, the cystic duct or the main pancreatic duct, *re-inserting the guidewire* may be of help. Under these circumstances radiographic imaging represents an expedient aid (10).

Loss of access to the BT by the cholangioscope

- Not uncommon in two situations: when an unstable duodenoscope falls back into the stomach and when working at the distal end of the common bile duct (because of distal strictures or impacted gallstones).
- When cannulation is lost at the biliary tract, it may be directly regained *with or without the aid of a guidewire*. It is advisable to leave the cholangioscope just short of the duodenoscope's elevator bridge, and cannulate just as we would with a sphincterotome.
- When cannulating without a guidewire, achieving an appropriate orientation of the cholangioscope tip using the up/down, right/left knobs may be helpful. Keeping the securing or locking system halfway facilitates the cholangioscope's distal end to maintain the desired shape during the cannulation maneuver.

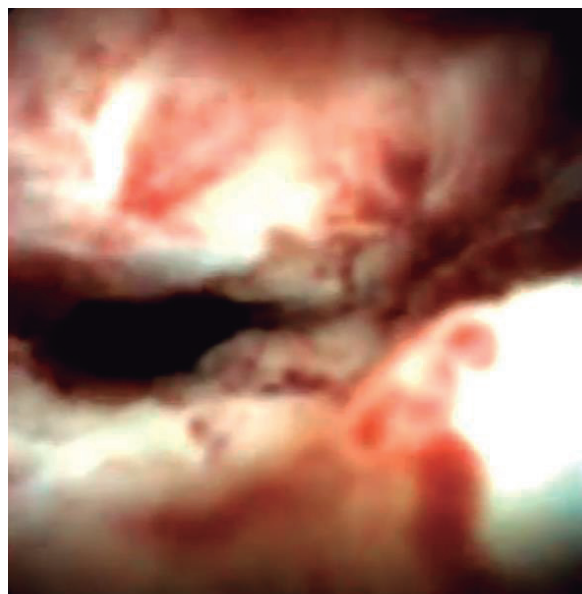


Fig. 3. Cholangiocarcinoma. Choledochal lumen stricture with dilated, tortuous blood vessels.

INDETERMINATE STRICTURE STUDY

Recommendations include:

- In case of stenotic, extrahepatic lesions, it is recommended that intrahepatic ducts also be examined to rule out extended or synchronous lesions (1). *The proximal point reached within the BT* should be detailed, as well as the topography of the analyzed biliary ducts.
- *Minimization of the volume* of saline instilled (5).

The direct-view study of biliary strictures has a high diagnostic certainty. However, biopsy collection is mandatory in the face of any dubious or suspicious-for-malignancy lesion.

The characteristics of a malignant lesion include:

- Neovascularity. Dilated, tortuous vessels, vascular leaks.
- Friability.
- Exophytic/nodular tissue.
- Elongated villi with a central vessel.
- Luminal reduction: concentric or non-concentric.
- Abnormal vascular pattern with prominent blood vessels, absence of fine vascular network (11) (Fig. 3).

The characteristics of a benign lesion include:

- Absence of friability.
- Nodular tissue may be present but is seldom exophytic.
- Fine vascular pattern and network.
- Absence of prominent vessels and vascular lakes.
- Scarring.
- Absence of neovascularity (5).

The study of the BT with a cholangioscope may provide valuable data for the assessment of indeterminate strictures

by allowing the examination of both the involved and adjacent epithelium (synchronous lesions). Occasionally, these lesions are patchy and difficult to visualize. Such is the case of the so-called biliary intraepithelial neoplasia (BillIN). This argument would justify "mapping" the area with perilesional biopsy taking around surgically resectable, malignant biliary lesions. This is a cholangioscopy indication currently in the evaluation phase (11-15).

Biopsy taking

Recommendations are as follows:

- For advancing biopsy forceps, *the same considerations on angles and axes* hold true as previously detailed for cholangioscope progression. Importantly, forceps progression should ensue with very short, controlled movements to avoid bending or crimping. Forceps lubrication with a silicon spray may be helpful, as may instructing the assistant to keep the cups closed without exerting pressure on the handle.
- *Radiographic imaging may help* identify the point where forceps advancement is difficult.

The flexion curvature of the distal duodenoscope represents the point where forceps advancement is most difficult. At this level, the angle becomes more acute. A useful trick to overcome this is to leave the forceps in that place and then *move the cholangioscope into the common bile duct*. The forceps will then be drawn along with it.

- Once the forceps has overcome the distal end of the cholangioscope, the latter may be withdrawn to position the forceps facing the target lesion.
- Once the site to be biopsied is identified, angulation maneuvers using the SpyGlass® knobs or their brakes may be of help.

- The *minimum recommended number of biopsy samples* from the target lesion is four.
- Each collected sample should be examined by an assistant to make sure tissue is present. To this end, a magnifying glass attached to the working table may be useful.
- The pathology study of smaller samples may involve a special intricacy. The figure of an *adept pathologist*, expert in this type of sample, may enhance the technique's overall efficacy. Furthermore, an assessment by a pathologist present in the endoscopy room may help speed up the diagnosis or decision making for indeterminate lesions (5).

BILIARY LITHOTRIPSY

Biliary lithotripsy is a therapeutic technique involving the use of shock waves to break up gallstones. Lithotripsy under cholangioscopic guidance may be of two types: electrohydraulic lithotripsy (EHL) and laser lithotripsy. Both are highly effective for extrahepatic as well as intrahepatic lithiasis.

Electrohydraulic lithotripsy (EHL)

EHL uses bipolar electrical technology. The tip of an EHL probe has two coaxially isolated electrodes. When the power source is on, a spark jumps between the electrodes and under a physiological saline solution, generates high-voltage hydraulic pressure waves that, on collapsing, give rise to secondary pressure waves called shock waves (16-18) (Fig. 4).

Recommendations for using EHL include:

- It must be used in a *liquid medium*, with the BT filled up with saline solution. Under immersion the procedure magnifies the effect 10-fold.
- The EHL probe has a *diameter* of 1.9 French (0.66 mm) and is single use.
- *Secure the tip* of the probe or fiber to the Y-port attachment of the SpyGlass®. It is important to maintain the fiber tip 3-4 mm outside the working channel of the SpyGlass® to avoid damaging the high-tech components at the cholangioscope's distal end.
- It is also important that the *catheter tip be placed at < 2 mm* from the lithiasis, albeit avoiding direct contact with the stones. At that distance, waves hit stone surfaces more effectively. Touching stones with the probe or fiber tip should be avoided, as this may impair performance and durability, and perforate rather than fragment gallstones. In contrast, when the catheter tip is positioned over 4 mm away, waves may vanish before hitting their target.
- When the *lithiasis is very close to the duodenal papilla*, lithotripsy becomes more challenging as the above-mentioned recommended distances cannot be kept. In such cases, pushing the gallstone further back into the main bile duct may be of help.
- Power density is obtained by combining shot frequencies of 1-20 per second and voltages of 50 to 100. *No efficacy parameters have been defined* that are valid for all types of lithiasis. Starting with a low

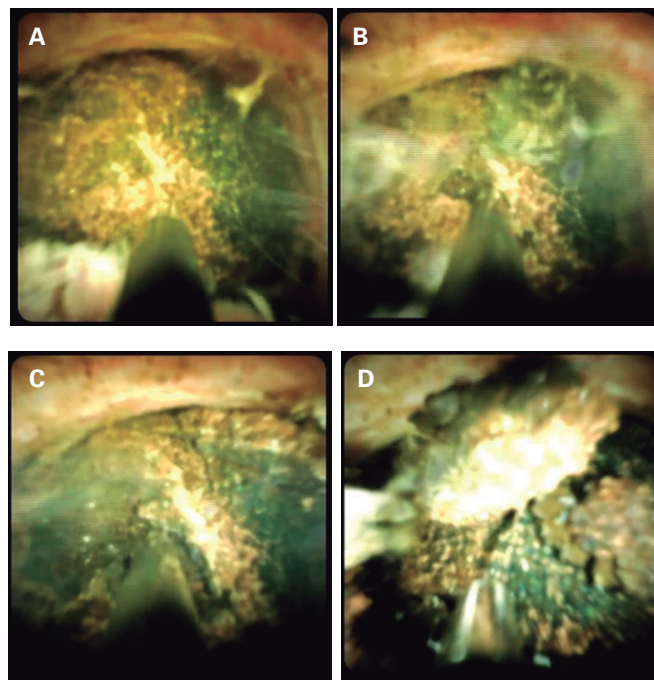


Fig. 4. A. Biliary lithiasis. EHL catheter directed towards the central core of the lithiasis. B. Biliary lithiasis. EHL catheter. The first fragments appear. C. Biliary lithiasis. EHL catheter. A crack develops in the lithiasis. D. Biliary lithiasis. EHL catheter. Major fragments.

energy level and rising power output gradually according to results is recommended.

- When possible, biliary lithotripsy should *start* with the stone nearest the duodenal papilla. This allows access to more distal stones.
- Whenever possible, the *EHL catheter should be directed towards the central part of the stone*. The stone may be touched when necessary as a reference for measurements. If the catheter's tip cannot be centered, the probe may be triggered tangentially; this may result in stone "chipping", allowing the probe to be better positioned (Fig. 4).
- Stones should be broken up into *tiny fragments*. Their removal is at times helpful to clear the field and then move on with the lithotripsy.
- *Using more than one probe* may be necessary for the complete destruction of large or multiple stones.
- Having a wide sphincterotomy available facilitates the procedure and reduces trauma when fragments of chipped stones are removed (Fig. 5).
- The *primary risk of EHL is perforation* of the BT, which may occur when the probe comes into contact with the wall. Perforation may also occur because of the extreme temperature at the stone's surface and the duct tissues around it. This is usually due to prolonged EHL use. The duct must be frequently irrigated when performing a lithotripsy as this will keep clear the field of view, and will also cool down the duct. *Bleeding* may occur when the probe touches the BT (5).

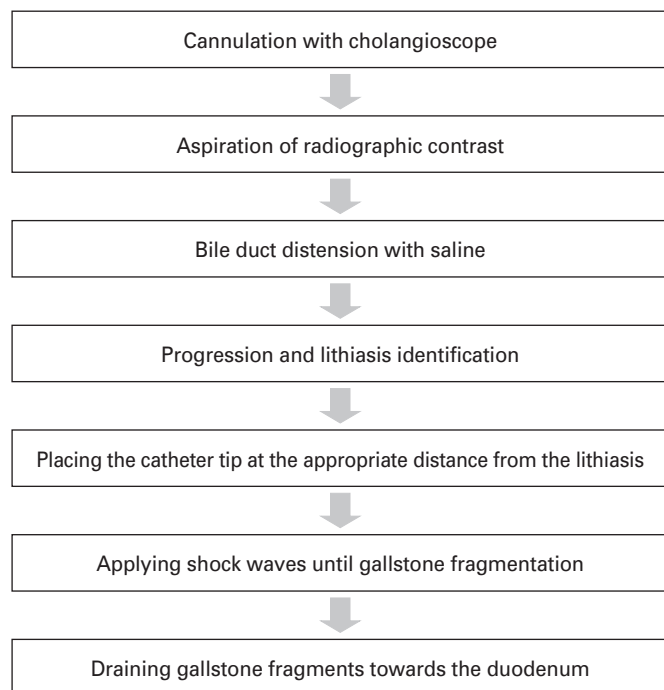


Fig. 5. Algorithm showing the steps of cholangioscopy in association with EHL.

Laser lithotripsy

In contrast with the shock waves of EHL, the laser produces steam bubbles. A steam bubble rapidly expands to generate a mechanical shock wave. A holmium Nd-YAG laser device is made up of flexible quartz fibers.

- The laser used for cholangioscopic biliary lithotripsy is the same usually used for urinary lithiasis.
- The wavelength of laser light lies near the infrared band on the spectrum and delivers high-power pulses between 500 and 1,000 MJ.
- As with EHL, the fiber end should be placed less than 2 mm away from the lithiasis.
- The laser probe may be moved along a cholangioscope's work channel with some difficulty, which may require repositioning maneuvers and entail risk of losing insertion into the biliary tract.
- Both EHL and laser lithotripsy have demonstrated similar effectiveness and safety levels (technical success, 96.7 % for EHL vs 99 % for laser lithotripsy) (19). Opting for either system will rather depend on availability and experience.

PANCREATOSCOPY

Basics

Recommendations include:

- *Pancreatic sphincterotomy* should be adequately sized for the passage of a pancreatoscope. This reduces air in the pancreatic duct and prevents excessive filling with saline.

- A limitation of pancreatoscopy using a SpyGlass® is conditioned by *the diameter of the duct being examined*. Remember that a SpyGlass® has a 10-French outer diameter, equivalent to 3.3 mm or 0.131 inches.
- First apply suction for radiographic contrast, then fill up with saline solution.
- The *instilled volume* of saline should be the smallest possible.
- Use 20-cc Luer Lock syringes rather than a mechanic aspirator for suction. It is easier to control and less likely to induce excessive luminal collapse.
- Maintaining suction for the *CO₂ insufflated into the duodenum* is useful to reduce its passage to pancreatic ducts.
- *Progression ensues on a guidewire* (same type used for the BT), especially in the case of chronic pancreatitis.
- *Examination of the main pancreatic duct* should be performed from head to tail.
- *Avoid suctioning the duct wall*.
- It is advisable to use *intermittent radiographic monitoring* to establish location.
- There is a greater need for controlling the SpyGlass® tip when maneuvering inside the main pancreatic duct, which has a higher number of *angled curves*.
- Placement of a *plastic pancreatic stent* is highly advisable to reduce post-pancreatoscopy acute pancreatitis except in case of intraductal mucinous papillary neoplasm, such as mucus production that may occlude the stent's drainage holes (6,20,21).

Pancreatic lithotripsy

Difficulty in the management of these patients has to do with the ability to negotiate associated strictures, guidewire progression towards the lithiasis and lithiasis-associated duct curves. Patients undergoing pancreatoscopy for pancreatic lithotripsy usually have chronic pancreatitis and main duct stricture, which require dilations in order to advance.

Recommendations for pancreatic lithotripsy include:

- Importantly, the fiber tip should be kept at 3-4 mm out of the scope to avoid potential damage to the pancreatoscope end.
- The fiber tip should be placed *at < 2 mm* from the stone when firing the laser or EHL device.
- *Fiber contact with the lithiasis should be avoided* as it may impair fiber performance and durability, as well as induce perforation and will not achieve fragmentation.
- Stones should be broken up into the smallest fragments possible.
- *Given their usual hardness, pancreatic stones* often require using maximum power to attain fragmentation. However, starting at a low power and then gradually increasing output is always recommended.
- *Frequently irrigate the pancreatic duct* during lithotripsy to keep the field of view clean. This will also help to cool down the duct (5,9,22-24).

Intraductal mucinous papillary tumor (IMPT)

Cumulative experience refers to main duct IMPT, since moving through a secondary branch IMPT is challenging,

even in the presence of dilation. The SpyGlass® DS II has a knob turning limited to only 30°.

Recommendations are as follows:

- *Pancreatic sphincterotomy* is not required for some IMPTs with an open papilla.
- It is important that *mucus be drawn out of the pancreatic duct* using a balloon. Mucus tends to be dense and thick, hence difficult to suction out.
- *Spyglass-directed biopsy may provide a diagnosis in 90 % of patients.*
- Currently, *the primary use of pancreatoscopy for IMPTs is preoperative* with the purpose of assessing extent, ruling out synchronous lesions, and delimiting resection margins (5,25,26).

Indeterminate lesions or strictures of the pancreatic duct

Indeterminate strictures of the pancreatic duct represent rare cases where no masses are observed during endoscopic ultrasound. They may correspond to scarring secondary to prior lesions or to lesions such as pancreatic intraepithelial neoplasia (PanIN).

For these conditions, recommendations include:

- *Dilate stricture before pancreatoscopy* when possible with a balloon. Dilation with a balloon 4 mm in diameter and 2 cm in length usually suffices.
- Whenever an abnormality is seen with the pancreatoscope, *a radiographic image should be obtained* for improved assessment of its location.
- Attempts should be made to advance the pancreatoscope *to the tail* of the pancreas.
- *Biopsy samples should be taken for all abnormalities.*
- *At the stricture multiple biopsies should be collected, at least four (5).*

FCP COMPLICATIONS

Complications arise in all phases of the procedure. During introduction of the duodenoscope the complications are the same as those of ERCP. This includes duodenal perforation, which may be resolved with endoscopic techniques such as clips or transmural clips, or may require surgery. A careful technique and adjusted indication is best for prophylaxis.

During the biliary cannulation phase and sphincterotomy, possible adverse events include those that may develop during conventional ERCP: acute pancreatitis, bleeding, perforation, cholangitis and acute cholecystitis. For the prevention of acute pancreatitis, the aforementioned current guidelines and recommendations should be followed, and pancreatic stents should be placed whenever necessary (6-8). When the above adverse events develop, they usually require medical management.

With regard to bleeding and perforation, the best prophylaxis is again a correct technique with a gradual, properly proportioned sphincterotomy. However, these complications may occur and their endoscopic management should

be attempted: most bleeding events are mild and may be managed with usual endoscopic techniques such as hemostatic injections or clips. Although in some cases, recourse to techniques such as balloon compression or placement of fully covered biliary stents is required. For perforations, directly placing a fully covered biliary stent and initiating conservative treatment is advisable. Failed cases or those with a poor outcome will require surgery.

FCP adds a greater risk of adverse effects to ERCP: cholangitis 1 % vs 0.2 %; acute pancreatitis 2.2 % vs 1.3 %; perforation 1 % vs 0.3 %, respectively (22). Gas embolism has also been reported during FCP (27). These adverse effects are usually mild and should be managed conservatively. Biliary tract perforation or bleeding may develop from the cholangioscope, guidewire or lithotripsy probe insertion. Management should be conservative with placement of fully covered biliary stents (5,22,26,28).

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