Communication from the ASGE Technology Committee

TECHNOLOGY STATUS EVALUATION REPORT

Biliary and pancreatic lithotripsy devices

Prepared by: ASGE TECHNOLOGY COMMITTEE

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This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

Background and Aims: Lithotripsy is a procedure for fragmentation or destruction of stones to facilitate their removal or passage from the biliary or pancreatic ducts. Although most stones may be removed endoscopically using conventional techniques such as endoscopic sphincterotomy in combination with balloon or basket extraction, lithotripsy may be required for clearance of large, impacted, or irregularly shaped stones. Several modalities have been described, including intracorporeal techniques such as mechanical lithotripsy (ML), electrohydraulic lithotripsy (EHL), and laser lithotripsy, as well as extracorporeal shock-wave lithotripsy (ESWL).

Methods: In this document, we review devices and methods for biliary and pancreatic lithotripsy and the evidence regarding efficacy, safety, and financial considerations.

Results: Although many difficult stones can be safely removed using ML, endoscopic papillary balloon dilation (EPBD) has emerged as an alternative that may lessen the need for ML and also reduce the rate of adverse events. EHL and laser lithotripsy are effective at ductal clearance when conventional techniques are unsuccessful, although they usually require direct visualization of the stone by the use of cholangiopancreatoscopy and are often limited to referral centers. ESWL is effective but often requires coordination with urologists and the placement of stents or drains with subsequent procedures for extracting stone fragments and, thus, may be associated with increased costs.

Conclusions: Several lithotripsy techniques have been described that vary with respect to ease of use, generalizability, and cost. Overall, lithotripsy is a safe and effective treatment for difficult biliary and pancreatic duct stones. (Gastrointest Endosc 2018;3:329-38.)

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have an impact on the practice of GI endoscopy. Evidence-based methods are used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a search of the MAUDE (Manufacturer and User Facility Device Experience) database (U.S. Food & Drug Administration, Center for Devices and Radiological Health) to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

Technology Status Evaluation Reports are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the Committee, and approved by the Governing Board of the ASGE. When financial guidance is indicated, the most recent coding data and list prices at the time of publication are provided. For this review the MEDLINE database was searched through February 2017 for articles related to biliary and pancreatic lithotripsy by using relevant

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keywords including "lithotripsy," "mechanical," "electrohydraulic," "laser," and "shock wave" as well as "bile duct," "choledochus," "gallstone," "gallbladder," "pancreas," "choledochoscope," "cholangioscope," and "pancreatoscope."

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BACKGROUND

Lithotripsy is a procedure for the destruction or fragmentation of stones to facilitate their removal or passage from the biliary or pancreatic ducts. Lithotripsy may be performed by intracorporeal approaches using mechanical, electrohydraulic, or laser devices at the time of endoscopic (via ERCP) or percutaneous access, or by extracorporeal shock wave lithotripsy (ESWL). This document will review devices and methods for biliary and pancreatic lithotripsy and is an update of a previously published ASGE Technology Committee document on this topic.[1]

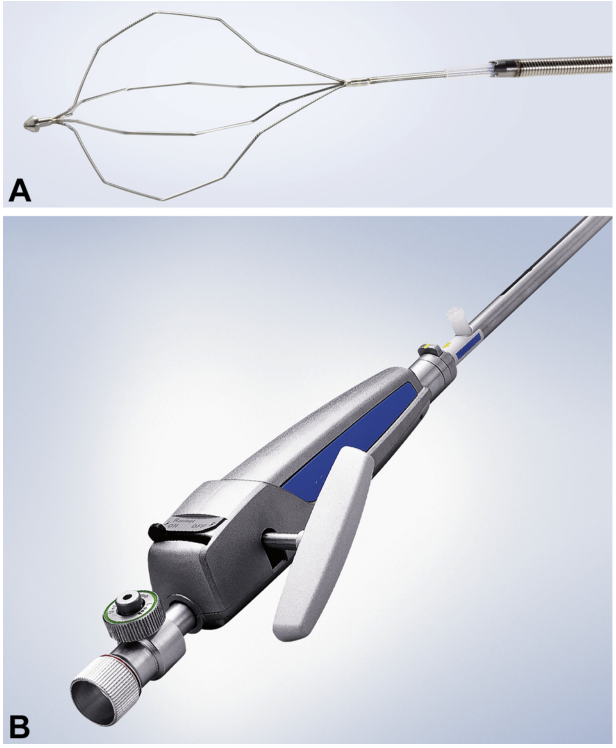

Figure 1. Example of an integrated mechanical lithotripter basket with a plastic inner sheath and metal outer sheath (**A**) and handle (**B**). (Used with permission from Olympus.)

TECHNOLOGY UNDER REVIEW

Mechanical lithotripsy

A mechanical lithotripter consists of a wire basket, a metal sheath, and a handle that provides mechanical retraction of the basket into the metal sheath, thereby directing a crushing force to stones captured within the basket. There are 2 basic designs of mechanical lithotripters. Integrated devices incorporate all components of the system and are designed for use through the operating channel of the duodenoscope (Fig. 1). Salvage devices consist of only the metal sheath and handle and are typically used when a non–lithotripsy-compatible basket containing a stone becomes impacted in the bile or pancreatic duct during attempted stone extraction (Fig. 2).

Integrated lithotripters function like a standard stone basket until lithotripsy is required. They can be used on stones anywhere within the ducts and can be used multiple times during the same procedure. Both single-use and reusable systems are available in a variety of basket sizes. Wire-guided baskets are available. Some units require assembly before use.

Salvage devices are designed to be applied over a variety of stone-removal baskets, but not all baskets are lithotripter-compatible. Basket designs ideally include failure points that break in a manner that allows basket disimpaction from around the stone when an application of maximum force fails to achieve stone fragmentation. The use of a salvage lithotripter with a noncompatible basket may result in wire fracture at an unpredictable site along the length of the device, possibly away from the actual basket. When salvage lithotripsy is required, the basket handle is cut off, and the plastic catheter covering the wires is removed. The metal lithotripter sheath is then advanced over the wires of the impacted basket to the level of the stone, and the lithotripsy handle is attached to the metal sheath and the basket wires. Under fluoroscopic guidance, rotation of the handle retracts the basket and the stone against the sheath, breaking the stone or the basket and allowing the basket to be removed. Some models can be advanced through the endoscope, whereas others require removal of the endoscope before positioning of the metal sheath. Specifications of commercially available integrated lithotripters and salvage mechanical lithotripters are given in Table 1.

Electrohydraulic lithotripsy

Electrohydraulic lithotripsy (EHL) systems consist of a bipolar probe and a charge generator. When a charge is transmitted across the electrodes at the tip of the probe, a spark is created. This induces expansion of the surrounding fluid, resulting in an oscillating shock wave of pressure that is typically adequate to fragment most stones. Saline solution irrigation is required to provide a medium for shock wave transmission, to assure visualization, and to flush away debris. The procedure is usually

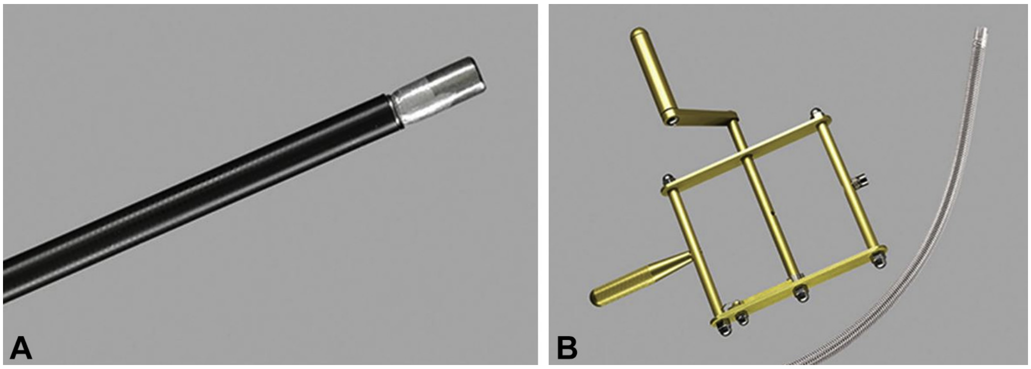

Figure 2. Salvage lithotripter consisting of (**A**) a metal sheath and (**B**) a handle. (Used with permission from Cook Medical.)

performed under direct cholangioscopic or pancreatoscopic guidance to avoid errant application of shock waves that may potentially cause ductal trauma and perforation. However, lithotripsy probes have been used with fluoroscopic guidance only, facilitated by balloons or basket catheters that center the probe. The probe is directed at the stone and is optimally advanced ≥5 mm from the tip of the endoscope and positioned 1 to 2 mm from the stone.[2] EHL is activated by a foot pedal. Stone fragments are then removed by standard means.[3] EHL destruction of a biliary stone under cholangioscopic guidance is demonstrated in Video 1 (available online at www.VideoGIE.org).

The Autolith and newer Autolith Touch EHL units (Nortech; Northgate Technologies Inc, Elgin, Ill, USA) are the only EHL systems that have received clearance by the U.S. Food & Drug Administration (FDA) for biliary stones. The Autolith Touch system allows selection between low-, medium-, and high-power settings and the number of pulses delivered by a single foot pedal activation. The manufacturer recommends beginning at low power and suggests that 3 to 5 pulses per activation is ideal for most procedures. The legacy Autolith system allows titration of power (10% to 100%), shot frequency (1/sec to 30/sec), and number of shots delivered by a single foot pedal activation (1 to 60). The manufacturer recommends beginning with 30% to 40% power and 3 to 5 shots delivered per foot pedal activation. Lower shot frequencies may suffice for impacted stones, whereas fewer shots at a higher shot frequency are suggested for freely mobile stones. Pancreatic lithotripsy is a common off-label use for these EHL systems. Anecdotally, higher-power settings are needed for fragmentation of pancreatic stones. The Nortech bipolar biliary EHL probe is 1.9F (0.66 mm) and is available in 250-cm and 375-cm lengths. The probes are single-use items; using higher-power settings and a higher number of shots may reduce probe life. Complete destruction of large or multiple stones may therefore require more than 1 probe during the same session.

Laser lithotripsy

Several laser lithotripsy systems have been used for biliary and pancreatic applications. Focusing laser light of a high-power density on the surface of a stone creates a plasma composed of a gaseous collection of ions and free electrons. This plasma bubble oscillates and induces cavitation with tensile and compressive waves that fracture the stone surface. Fragmentation of a large bile duct stone using laser lithotripsy under cholangioscopic guidance is demonstrated in Video 2 (available online at www.VideoGIE.org).

Holmium:yttrium aluminum garnet (YAG) lasers are commercially available (Lumenis Inc, San Jose, Calif, USA), are widely used for urinary tract stones, and have FDA clearance for the treatment of gallbladder and bile duct stones as well. The laser-light wavelength (2100 nm) is in the near-infrared spectrum and delivers high-energy pulses of about 500 to 1000 mJ.[4] The single-use laser delivery fibers are up to 4 m long and are available in multiple diameters; 550- or 1000-μm fibers are used most commonly for biliary applications. They fit through the working channels of most cholangioscopes and pancreatoscopes. As with EHL, direct visualization of the stones is generally recommended to prevent ductal trauma. However, stones have also been targeted by the use of centering balloons with fluoroscopic guidance alone.[3,4] Power settings are usually 0.6 to 1.0 J at 6 to 10 Hz for total laser energy of 12 kJ.[5] These laser lithotripter units are typically wheeled or placed on a wheeled cart, weigh 84 to 303 kg, and require 110 AC or 220-volt electricity, depending on the wattage of the unit.

The frequency-doubled double-pulse neodymium:YAG (FREDDY) laser is FDA cleared for bile duct stones. The FREDDY laser uses wavelengths of 532 and 1064 nm and generates up to 120 to 160 mJ (approximately 24 mJ at 532 nm). Laser-pulse duration is 1.2 ms at 160 mJ, with single or dual pulse at adjustable rates of 1, 3, 5, or 10 Hz with standard 110-volt AC electricity, or 15 or 20 Hz with 220-volt electricity. However, the latter pulse frequencies are rarely necessary. The manufacturer recommends initial settings of 120 mJ single pulse and 3 to 5 Hz repetition rate, which

TABLE 1. Mechanical lithotripters

Design type	Manufacturer	Device name	Model	Cost: initial /per-use*	Assembly required	Contrast injection capability	Working channel, mm	Crush >1 stone
Integrated								
	Boston Scientific Corp							
		Trapezoid RX	M00510860	$933/$483	No	Yes	3.2	Yes
		(4 open basket diameters, 1.5 - 3 cm)	M00510870	$933/$483	No	Yes	3.2	Yes
			M00510880	$933/$483	No	Yes	3.2	Yes
			M00510890	$933/$483	No	Yes	3.2	Yes
		Alliance II†	M00550620	$450	NA	NA	NA	NA
	Cook Endoscopy							
		Fusion	FS-LXB-2X4	$419	No	Yes	4.2	Yes
			FS-LXB-3X6	$419	No	Yes	4.2	Yes
	Olympus America Corp							
		LithoCrushV	BML-V242QR-30	$1531/$620	Yes	Yes	4.2	Yes
			BML-V232QR-30/26	$1531/$620	Yes	Yes	3.2	Yes
			BML-V442QQR-30 (wire-guided)	$1531/$620	Yes	Yes	4.2	Yes
			MAJ-441†	$911	NA	NA	NA	NA
Salvage‡								
	Cook Endoscopy							
		Conquest TTT	TTCL-1 (cable)	$202	Yes	Yes	3.2	No
			TTCL-10 (cable)	$202	Yes	Yes	3.7	No
		Soehendra	SLC-2 (cable)†	$202	Yes	No	Remove scope	No
			SLH-1†	$368	NA	NA	NA	NA
	Olympus America Corp							
			BML-110A-1†,§	$692	NA	NA	NA	No
			MAJ-403 (sheath alone)†	$114	Yes	No	Remove scope	No

NA, Not applicable.
*Initial cost includes complete system for 1 use, with all reusable components and 1 basket. Per-use cost includes the cost for single use of a new disposable component and/or basket.
†Reusable.
‡Exclusive of the cost of the entrapped basket.
§Includes both emergency sheath and handle.

can be increased to 160 mJ and 10 Hz. Double pulse at 120 or 160 mJ will cause the fiber to burn back into the buffer cladding of the laser more readily than single-pulse settings. The fibers (ThinFlex200Rplus) are 3.5 m long, have an outer diameter of 420 μm, and are marketed for reuse up to 10 times. These fibers can be inserted through the ports of most cholangioscopes and pancreatoscopes. The FREDDY laser fibers have also been used through the guidewire port of a stone-extraction balloon to maintain its position in the center of the duct.[6,7] This laser is portable, is 250 × 850 × 600 mm in size, and weighs 45 kg. The FREDDY laser is marketed in the United States as the U100Plus (World of Medicine, Orlando, Fla, USA).

Other lasers have been designed to limit duct injury by recognizing the difference between stone and tissue, and clinical outcomes with these systems have been reported in retrospective series.[5,8] However, these laser systems are not currently marketed or sold in the United States.

Extracorporeal shock wave lithotripsy

Extracorporeal shock wave lithotripsy (ESWL) uses shock waves generated outside the body by a lithotripter to fragment stones within the body. ESWL was developed for the treatment of urologic stones, and ESWL for biliary or pancreatic stones is thus often performed in collaboration with urology colleagues. It has been theorized that the passage of shock waves through the anterior and posterior surfaces of the stone liberates compressive and tensile forces, causing cavitation that leads to stone fragmentation.[3,8] All lithotripters have 3 components: a shock wave generator, which produces and focuses the shock waves; a means of coupling the shock wave to the patient; and an imaging modality to target the stone (Fig. 3).[9,10]

Shock wave generators use electrohydraulic, piezoelectric, or electromagnetic technology to generate shock waves.[11] Lithotripters have a focusing mechanism to concentrate energy onto the stone and thus reduce any damaging effects on the surrounding tissue.[8,10] Externally generated shock waves require transmission into the patient by a medium. Initial platforms used water as the medium, requiring the patient to be partially submerged in a water basin. In newer systems, coupling is achieved by the use of water-filled cushions brought into contact with the skin using a gel.[1,11]

Accurate targeting of the shock waves on the stone is essential for effective lithotripsy and is achieved by use of an imaging modality.[11-13] Fluoroscopy and US have been used for this purpose. Because fluoroscopy can detect only radiopaque stones, an intraductal stent may be placed to allow focusing of shock waves along the duct to target additional radiolucent stones. US can detect both radiopaque and radiolucent stones, but interposed air-filled intestinal loops may hamper the detection of pancreatic and distal biliary stones.

ESWL systems are available from multiple manufacturers. Some ESWL systems are FDA cleared for the treatment of biliary stones. In clinical practice, these systems are used much more frequently for pancreatic stones, which is an off-label indication for all systems.

Figure 3. Example of an ESWL system including the generator and imaging apparatus with a patient in position. *ESWL,* Extracorporeal shock-wave lithotripsy. (Used with permission from Tailly GG. Extracorporeal shock wave lithotripsy today. Indian Journal of Urology 2013;29:200-7.)

INDICATIONS

Intraductal lithotripsy is used for stones in the intrahepatic and extrahepatic bile ducts and for obstructing stones in the pancreatic duct that cannot be removed by conventional methods. ESWL is used for the same indications and rarely as an adjunctive or primary therapy for gallbladder stones.

EFFICACY AND COMPARATIVE STUDIES

Biliary lithotripsy

Several large case series have demonstrated that mechanical lithotripsy (ML) leads to complete bile duct clearance in about 80% to 90% of patients; however, 20% to 30% of patients require more than 1 procedure.[11,14-24] ML is less likely to be successful with larger and impacted stones.[21,24] In a series of 209 patients with a median stone diameter of 18 mm, the rate of successful stone clearance fell from 87.6% to 67.6% for stones >25 mm.[21] Another series of 116 patients found that the cumulative probability of bile duct clearance for stones >28 mm was 68% compared with >90% for those <10 mm.[24]

Recently, the use of endoscopic papillary balloon dilation (EPBD) has been shown to be an effective alternative to ML for large bile duct stone removal. A meta-analysis including 6 randomized controlled trials (RCTs) comparing endoscopic sphincterotomy (ES) combined with conventional techniques versus ES plus EPBD demonstrated that the 2 approaches were equally effective for stone clearance. However, EPBD was also associated with a significant reduction in the need for ML, particularly for stones >15 mm (odds ratio, 0.15; 95% confidence interval [CI], 0.03-0.68; $P = .01$), and a significantly lower rate of perforation.[25] A second meta-analysis including 902 patients from 7 RCTs similarly showed that ES plus EPBD was associated with a reduced need for ML compared with ES alone (15% versus 32%; RR = 0.49 [CI, 0.32, 0.74]; $P = .0008$) and was also associated with a reduction in the overall rate of adverse events (11% versus 18%; relative risk = 0.58 [CI, 0.41, 0.81]; $P = .001$).[26]

Case series of patients with bile duct stones refractory to standard endoscopic therapy report stone fragmentation and clearance in 77% to 100% using EHL.[2,3,27-35] Repeated procedures and/or other forms of lithotripsy may be required. Laser lithotripsy has a potential advantage of relatively precise targeting of stones that may reduce the risk of injury to surrounding tissue.[36] In several small series, the holmium:YAG laser has been reported to result in total clearance of intrahepatic and extrahepatic bile duct stones in 85% to 100% of patients.[6,7,37-54] Similar results have been achieved with a variety of lasers that are currently unavailable in the United States.[3,5,7,55]

Percutaneous approaches to EHL or laser lithotripsy may be used for intrahepatic stones, with reported rates of ductal clearance in 80% to 97% of patients.[56-63] However, multiple (3 to 6) procedures may be required, and high rates of cholangitis and stone recurrence rates have been reported, likely resulting from retained occult stone fragments and intrahepatic strictures. As such, percutaneous drains are frequently left in place for several weeks in these patients.

Studies using ESWL for clearance of bile duct stones refractory to endoscopic treatment have reported a complete stone clearance rate of 78% to 90%.[30,64-68] More than 1 ESWL session may be required to achieve adequate stone fragmentation to allow complete ductal clearance. ERCP is commonly performed after an ESWL session for removal of stone fragments.[65,68,69] Fragmentation of the stones in response to ESWL and thus complete ductal clearance may be inversely related to stone size.[70] Obesity has been suggested as a risk factor for ESWL failure and increased procedural adverse events, whereas intravenous administration of cholecystokinin during ESWL has been associated with a higher rate of complete stone clearance.[64,71,72] Recurrence of bile duct stones after successful ESWL and ductal clearance has been reported in 14% to 23% of patients.[73,74]

ESWL is rarely performed for management of refractory biliary stones in the United States, and most centers prefer cholangioscopy-guided laser or EHL for this purpose.[75] Two RCTs have compared ESWL with laser lithotripsy in this setting. In 1 trial, 9 of 17 (52.4%) patients undergoing ESWL achieved complete stone clearance compared with 14 of 17 (82.4%, $P = .07$) for those undergoing laser lithotripsy.[55] In another trial, rates of stone clearance were 73% (22/30) and 97% (29/30) for ESWL and laser, respectively ($P < .05$).[76] In both trials, the required number of treatment sessions was also significantly lower in favor of laser lithotripsy. However, in another RCT, complete bile duct clearance was observed in similar proportions of patients randomized to EHL and ESWL, at 74% and 79%, respectively.[30] In these 3 RCTs, crossing over to the alternative form of lithotripsy improved the overall clearance rates to 94% to 100%.[30,55,76] In a retrospective case series of 108 patients with failed biliary stone extraction using usual methods, success was achieved with ML in 33 patients, with EHL in 65 patients, and with ESWL in 7 of 10 patients (all with intrahepatic stones) for an overall success rate of 95%.[31] ESWL has been used for fragmentation of gallbladder stones, but due to high stone recurrence rates and the minimal morbidity of laparoscopic cholecystectomy, this method is rarely used.[77]

Pancreatic lithotripsy

Multiple case reports and case series describe the successful management of pancreatic duct stones with ML[78,79] and EHL.[29,79-84] Symptom improvement is seen in the majority of patients with complete or partial duct clearance.[78-80] A multicenter retrospective study of holmium:YAG laser lithotripsy of pancreatic stones in 28 patients demonstrated complete duct clearance in 79%, with improvements in pain and reduction in use of narcotics in 89% of patients.[85] Other small series describing laser lithotripsy for pancreatic stones have reported similar outcomes.[54,86,87]

A meta-analysis of 27 studies (n = 3189 patients) in the use of ESWL for chronic calcific pancreatitis reported a pooled estimate for complete ductal clearance rate of 71% (95% CI, 69-72.4) and partial ductal clearance rate of 22% (95% CI, 20.5-24.3).[76] Multiple sessions may be required to achieve ductal clearance.[88] This analysis also reported a significant improvement in quality of life, degree of pain, and narcotic use after ESWL therapy. Combining ESWL with ERCP may increase the rate of complete ductal clearance,[89] although in an RCT of 55 patients, the addition of ERCP to ESWL had no additive benefit in pain outcomes.[90] In patients with obstructive pancreatic duct stones, ESWL has shown efficacy in preventing recurrent attacks of acute pancreatitis.[91] A stone recurrence rate of 18% to 22% has been reported after successful ESWL of pancreatic duct stones.[88,89] There are no randomized studies comparing the efficacy of ESWL with other lithotripsy modalities for pancreatic ductal clearance.

EASE OF USE AND LIMITATIONS

Mechanical lithotripsy

For bile duct stones that prove refractory to removal with standard methods, ML and EPBD are appropriate considerations as a next step. Although ML is relatively straightforward to perform, some integrated lithotripters require assembly and greater knowledge of their function. Both integrated and salvage devices are stiff, are somewhat unwieldy, and require more time to operate than standard stone extraction devices.

EHL and laser lithotripsy

Available EHL generators are compact, easily mobile, and require no special electricity or protective wear. The holmium:YAG and FREDDY lasers are medium-sized, portable units that may require 220 volt electrical power. Personnel who use medical lasers need formal training in laser function and safety. Special protective eyewear must be used.[92] Before endoscopy is started, some lasers must be warmed up and calibrated. Both EHL and laser fibers may be difficult to manipulate through the working channel of a cholangioscope or a pancreatoscope because of their size and fragility. Prolonged application of energy and/or repeated procedures may be required to achieve complete stone fragmentation and clearance with either EHL or lasers.

EHL and laser lithotripsy are usually performed under direct visualization by use of a cholangioscope or a pancreatoscope passed through the duodenoscope. A single-use cholangioscopy platform (SpyGlass DS; Boston Scientific Corp, Natick, Mass, USA) allows for a single operator to control lithotripsy, whereas conventional "motherdaughter" cholangioscopes typically require 2 operators. During lithotripsy, stone fragments frequently obscure visualization, and continuous irrigation is required.[2,5]

Percutaneous transhepatic or T-tube access for cholangioscopy and antegrade application of EHL or laser lithotripsy allow for more direct ductal access and can potentially be performed with no sedation or lighter sedation. Disadvantages include the need for establishing large-caliber percutaneous access, logistical coordination with an interventional radiologist, and the requirement for a sterile field.

ESWL

Most pancreaticobiliary ESWL procedures in the United States are performed in collaboration with urologists because of their familiarity with the equipment and experience in treating urinary tract stones.[91] Adequate training has been shown to improve the success rate of ESWL for urinary stones among urologists[93] and is suggested for gastroenterologists who wish to perform pancreaticobiliary ESWL procedures.[94,95] Significant variation exists in clinical practice with regard to coordination of these procedures with colleagues in urology and anesthesia.

Because most biliary stones are radiolucent, placement of a biliary stent before ESWL is usually required to help with fluoroscopic stone localization.[75] In patients with obstructive pancreatic duct stones, a temporary pancreatic stent may assist in localization, reduce the risk of pancreatitis, and reduce the cumulative number of shock waves required for stone fragmentation.[91,96] After ESWL, stone fragments may or may not require endoscopic removal. Intravenous administration of secretin or cholecystokinin during ESWL may improve stone passage through the pancreatic and bile ducts, respectively.[72,97]

SAFETY

The majority of adverse events related to intraductal lithotripsy are associated with gaining pancreaticobiliary access (eg, ERCP or percutaneous transhepatic access) and with cholangiopancreatoscopy and include pancreatitis, hemorrhage, perforation, and sepsis.[56-60] There are no specific contraindications to intraductal lithotripsy beyond those associated with ERCP. Intraductal devices may be safely used sequentially during a single procedure (eg, EHL followed by ML). Biliary EHL and laser lithotripsy have been associated with cholangitis rates of up to 14%. Therefore, the use of prophylactic antibiotics should be considered, particularly in the setting of anticipated incomplete biliary drainage or with immunosuppressed patients such as liver transplant recipients.[98] Intraductal pancreatic lithotripsy has been associated with mild pancreatitis rates of up to 7%.[3,4,21,27] Additional rare adverse events include hemobilia, ductal perforation, and bile leak.[3] The need for prolonged irrigation during EHL and laser lithotripsy procedures may result in retrograde entry of saline into the stomach in quantities sufficient to pose a risk for aspiration; as such, consideration should be given to airway protection during these procedures. Basket impaction is a potential adverse event unique to ML.

ESWL for cholelithiasis has a reported adverse event rate of 30% to 40%.[1] Petechial skin lesions and biliary colic (related to passage of stone fragments) are common.[95] Adverse events have been reported in 14% of patients undergoing ESWL for choledocholithiasis, including pain, hemobilia, cholangitis, sepsis, pancreatitis, and hematuria.[1,95] The type of lithotripter used may affect the rate of adverse events.[67]

Adverse events associated with pancreatic ESWL have been reported in 5% to 10% of patients.[98,99] In a meta-analysis of 27 studies, post-ESWL pancreatitis was the most common adverse event, occurring in 4.2% of patients.[88] Other adverse events including cardiac arrhythmias, infections, bleeding, cholangitis, abdominal pain, pseudocyst formation, and perforation have been reported.[89,91,99,100] ESWL is contraindicated in pregnancy, coagulation disorders, calcified aortic aneurysms, and presence of lung tissue in the shock wave path.[101]

FINANCIAL CONSIDERATIONS

Mechanical lithotripters are relatively inexpensive compared with other lithotripsy modalities (Table 1). The Autolith Touch EHL generator (Northgate Technologies Inc, Elgin, Ill, USA) has a list price of $17,900, and the Micro II probes are $429 each. The P20 holmium:YAG laser (Lumenis Inc, San Jose, Calif, USA) is priced at $35,000, whereas fibers cost $490. Laser units may be available on a fee-per-use basis, with an additional charge for fiber reprocessing. The costs of choledochoscopes and repairs also need to be considered. Holmium:YAG and FREDDY lasers are frequently used in urology and may be a shared resource. ESWL lithotripters cost about $450,000 to $800,000; many large medical centers own them primarily for the treatment of urinary tract stones. In smaller institutions or surgery centers, leasing or renting of ESWL lithotripters is an option.

Endoscopic lithotripsy has a dedicated Current Procedural Terminology (CPT) code: 43265 (ERCP with endoscopic retrograde destruction, lithotripsy of calculus/calculi, any method). The CPT code for cholangioscopy/pancreatoscopy is 43273 (endoscopic cannulation of papilla with direct visualization of pancreatic/common bile duct [s]). This code is reportable in addition to the primary procedure code (eg, 43264 [ERCP with endoscopic removal of calculus/calculi from biliary and/or pancreatic ducts]). If 2 endoscopists are involved, 1 endoscopist may code 43264 and the other may use the cholangioscopy/pancreatoscopy and lithotripsy procedure code as outlined above. ESWL for biliary or pancreatic stones may be coded as CPT 43265 with a letter of explanation, or as CPT 47999 (unlisted procedure, biliary tract), or as CPT 48999 (unlisted procedure, pancreas) with an annotation that it is similar to CPT 50590 (renal lithotripsy, extracorporeal shock wave). There is a HCPCS (Healthcare Common Procedure Coding System) code S9034 (ESWL for gallstones), but this is not accepted by Medicare and many other providers.

The Centers for Medicare & Medicaid Services (CMS) has implemented Comprehensive Ambulatory Payment Classifications (C-APCs) wherein ERCP with lithotripsy may also be coded under APC group 5331 (complex GI procedures). Under the C-APC grouping, a single payment is provided for the primary service, whereas all other services performed on the same date are considered supportive to the delivery of the primary service. The average CMS payment for ERCP with lithotripsy using the C-APC 5331 group is $3941.

CONCLUSION

Lithotripsy is a relatively safe and effective treatment for difficult biliary and pancreatic stones. Many refractory stones can be removed with widely available techniques such as EPBD and/or ML. Other forms of lithotripsy are used less frequently and are generally limited to referral centers. EHL and laser lithotripsy usually require direct visualization with cholangiopancreatoscopy. ESWL is effective but expensive, often requires coordination with urologists and placement of internal drains or stents, and may require subsequent procedures for extraction of stone fragments.

DISCLOSURE

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; C-APCS, Comprehensive Ambulatory Payment Classification; CMS, Centers for Medicare and Medicaid Services; CPT, Current Procedural Terminology (https://www.asge.org/docs/default-source/education/Technology_Reviews/doc-enteral-nutrition-access-devices.pdf?sfvrsn=4); EHL, electrohydraulic lithotripsy; EPBD, endoscopic papillary balloon dilation; ERCP, endoscopic retrograde cholangiopancreatography; ES, endoscopic sphincterotomy; ESWL, extracorporeal shock wave lithotripsy; FDA, U.S. Food and Drug Administration; FREDDY, frequency-doubled, double-pulse neodymium; HCPCS, Healthcare Common Procedure Coding System; MAUDE, Manufacturer and User Facility Device Experience; ML, mechanical lithotripsy; RCT, randomized controlled trial; YAG, yttrium aluminum garnet.

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