Holmium-yttrium aluminum garnet laser lithotripsy in the treatment of biliary calculi using single-operator cholangioscopy: a multicenter experience (with video)

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Endoscopic retrograde cholangiography has been the criterion standard treatment of bile duct stones since 1974.[1,2] Use of standard endoscopic techniques such as sphincterotomy, extraction balloon, basket, or mechanical lithotripsy have been successful in approximately 90% of these patients.[3-5] Electrohydraulic (EHL)[6-8] and laser lithotripsy[9-12] were introduced in the mid-1980s as new treatment modalities for the 10% to 15% of patients with refractory stones and were found to be very effective. Because of the increased risk of heat-induced perforation, these techniques have been performed under either direct cholangioscopic visualization[7-10] or fluoroscopically with a stone/tissue detection system.[13,14] Because both systems were essentially limited to only major medical centers, EHL and laser lithotripsy have been used sparingly.

Single-operator steerable cholangioscopy (SOC) now permits the routine use of these technologies. Several lasers have been developed over the years for intraductal lithotripsy: pulsed-dye (coumarin green and rhodamine-6G) and pulsed solid state (neodymium-yttrium aluminum garnet [Nd-YAG]), frequency-doubled double-pulse yttrium aluminum garnet [FREDDY], alexandrite, and holmium: yttrium aluminum garnet [Ho:YAG]). Of these, the holmium laser is the newest laser lithotrite to be introduced to stone fragmentation. The aim of our study was to determine the safety and efficacy of this new technology in patients with difficult bile duct stones refractory to conventional endoscopic methods.

METHODS

Patients and endoscopic methods

Between July 2007 and December of 2009, 69 patients (26 men and 43 women) presented to 1 of 4 participating study centers for laser lithotripsy of bile duct stone(s). The median age of the patients was 60 years (range, 20-96 years). All patients had undergone at least 1 (mean, 1.4; range, 1-6) failed endoscopic retrograde biliary clearance procedure(s) before their referral. Patients deemed refractory had 1 or more of the following clinical situations: (1) stone exceeding 2 cm in size or multiple stones greater than 1 cm, (2) limited sphincterotomy or sphincteroplasty because of anatomic constraints (small papilla, periampullary diverticulum), (3) stones proximal to a stricture or in difficult locations (cystic or intrahepatic ducts), and (4) impacted stones. Patients presenting with refractory bile duct stones underwent ERCP with SOC-guided Ho:YAG laser lithotripsy using a 365-μm SlimLine disposable laser probe (Lumenis, Santa Clara, CA).

Before ERCP, written informed consent was obtained from all patients or from medical power of attorney/surrogates. The study protocol was approved by each institutional review board.

Sedation was administered in all cases by either the gastroenterologist in the form of conscious sedation with continuous monitoring of vital signs per unit protocol or by the attending anesthesiologist via general anesthesia

Abbreviations: EHL, electrohydraulic; FREDDY, frequency-doubled double-pulse yttrium aluminum garnet; Ho:YAG, holmium-yttrium aluminum garnet; Nd:YAG, neodymium-yttrium aluminum garnet; SOC, single-operator cholangioscopy.

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or MAC. ERCP with SOC was performed in the standard fashion.[15] All patients had a previously performed biliary sphincterotomy; however, extension of the existing sphincterotomy or balloon sphincteroplasty was performed occasionally to facilitate the procedure. Cholangiogram was performed to document the number of stones and size. SOC (SpyGlass, Boston Scientific, Marlborough, MA) was passed through the working channel of the duodenoscope and into the bile duct with or without a guidewire. Cholangioscopic visualization was assessed by the attending gastroenterologist on a quality scale of 1 to 4, 1 being poor visualization and 4 representing excellent visualization. Sufficient ($\geq$3) cholangioscopic visualization was achieved in all patients with aggressive intraductal water irrigation through the SOC at a rate of 80 mL/min.

Once the stones were visually identified, the laser probe was passed through the wire port of the SOC and placed in very close proximity to the stone. Laser power settings between 8 and 12 W were chosen to initiate lithotripsy. Short bursts were applied by stepping on the foot pedal attached to the laser generator for 5 seconds. This was repeated until adequate fragmentation was achieved. The total energy used per session for each patient was recorded. Stone fragments were then removed with standard extraction balloons and/or baskets. Ductal clearance was determined by occlusion cholangiogram or cholangioscopically.

All patients received an intraprocedural dose of intravenous antibiotic because of the possible risk of transient bacteremia and cholangitis. Repeat ERCP sessions were performed as necessary to achieve complete stone clearance. Safety and efficacy parameters were retrospectively collected using a standardized data collection form.

Laser lithotripsy

The laser used in this study was the Lumenis VersaPulse Ho:YAG transmitted via a GI SlimLine 365-µm silica fiber. Ho:YAG is a pulsed solid state laser with a wavelength of 2140 nm, which is very near the wavelength of water (1940 nm), and a pulse length of 500 µs. Power output was created using a 100-W generator by adjusting the energy (joules) and frequency (Hertz). In reference to our ex vivo animal studies, 8 to 12 W was used in bursts of no more than 5 seconds.[16] Bursts of laser were repeatedly delivered until adequate fragmentation was achieved or up to a total energy of 1 kW.

$$\text{Power (watts)} = \text{Energy(joules)} \times \text{Frequency (Hertz)}$$

$$\text{Total energy (kW)} = \text{Energy(kJ)} \times \text{Frequency (kHz)} \times \text{Time(seconds)}$$

Cholangioscopy

Cholangioscopic-guided laser lithotripsy was performed with the SOC (SpyGlass, Boston Scientific).

TABLE 1. Laser lithrotripsy patients

Total number of patients	69
Extrahepatic stones	57 (82%)
Intrahepatic stones	8 (12%)
Cystic duct stones	4 (6%)
Prior failed ERCPs, mean (range)	1.4 (1-6)
Sessions needed for stone clearance, mean (range)	1.2 (1-3)
Patients requiring 1 session	51 (74%)
Complete clearance of bile duct	67 (97%)
Procedural time, min, mean	69
Procedure-related adverse events	3 (4%)

RESULTS

Complete removal of bile duct stones was achieved in 67 of 69 patients (97%). In 51 of 69 patients (74%), biliary clearance was accomplished in 1 endoscopic session. Stones were located in the extrahepatic biliary system in 57 of 69 patients (82%), the intrahepatic biliary system in 8 of 69 patients (12%), and the cystic duct in 4 of 69 patients (6%). The 4 patients with cystic duct stones presented with biliary obstruction (Mirizzi's syndrome). The average stone size in patients with a single stone was 20.2 mm (range, 10-36 mm). Forty-seven of 69 (68%) patients had stones greater than 2 cm.

Successful extraction of stones in this group of patients occurred in 46 of 47 patients (98%) and was similar to that of the other patients (21/22, 95%). To facilitate removal of fragmented stones, endoscopic papillary balloon dilation (12-18 mm) and mechanical lithotripsy were performed in conjunction with laser lithotripsy in 7% and 17%, respectively. Laser lithotripsy failed in 2 patients who ultimately required biliary surgery. One patient had multiple large cystic duct stones, and the other failure occurred in a patient in which the stone (21 mm) was embedded in the common bile duct (12 mm).

The overall adverse event rate was 4.1%, with 2 patients experiencing minor bleeding of bile duct wall and 1 patient with mild post-ERCP pancreatitis. All patients recovered fully with conservative management (Table 1).

DISCUSSION

To our knowledge, this is the largest clinical study evaluating the technical success and safety of Ho:YAG laser lithotripsy for the management of difficult bile duct stones. The theory of laser (light amplification through stimulated emission of light) dates back to the turn of the 20th century. The first operating laser was