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Laser Lithotripsy of Difficult Bile Duct Stones Under an Integrated Automatic Stone-Tissue Detection System

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Abstract **We report our preliminary experience in the treatment of 16 CBD stone patients with a combination of ERCP with EST and rhodamine-6G dye laser (wavelength 595 nm) with an integrated automatic stone-tissue detection system. More than half (56.2%) of the patients had previous abdominal operations, whereas 37.5% had choledochotomy. Laser fibers were controlled by fluoroscopy only (blind technique). The laser energies used were 80-120 mJ and 5-8 Hz frequency. The sizes of stone ranged from 1.5 to 4.5 cm with an average of 2.7±1.0 cm. Laser lithotripsy resulted in successful fragmentation of stones in 14 of 16 patients (87.5%).**

In case of severe acute cholangitis (25%), temporary drainage by endoprosthesis in the CBD and appropriate adjunct therapeutic measures were used. After the infection subsided, usually one week, definitive laser treatment was then performed. The 30-day mortality rate was zero. We conclude that laser lithotripsy is an effective and safe treatment in a highly selected patient of difficult bile duct stones with considerable surgical risk.

Endoscopic sphincterotomy (EST) has become an established method of treating bile duct stones in patients with previous cholecystectomy and in elderly or high risk patient with the gallbladder in situ.[1] EST may be not amenable due to difficulty in cannulation of the papilla in some patients with anatomical abnormalities or previous gastroduodenal or biliary surgery. If the calculi are impacted or larger than 1.5 cm in diameter, the conventional endoscopic removal may be difficult.[2] Failure rate of EST and conventional technique is around 10-15 per cent of patients with bile duct stones.[1] The complementary method of choice is mechanical lithotripsy because of its simple and inexpensive nature. However, by using this procedure, the stones need to be captured in a basket which frequently fails in patients with stones larger than 1.5 cm in diameter.[3]

For this selected group of patient, intraductal litholysis, extracorporeal and various intracorporeal lithotripsy procedures under fluoroscopic or endoscopic guidance were proposed to overcome these limitations.[4-10] In our hospital, we found that common bile duct stones greater than 1.5 cm are difficult to remove by conventional techniques.

Nowadays, pulsed dye laser lithotripsy is one of the most promising methods for achieving a safe and rapid bile duct clearance.[10-12] Various efforts were made to develop laser systems offering effective bile duct stone fragmentation and a low risk of injury to the surrounding CBD wall. In pulsed dye laser systems, there are still a significant risk of duct perforation as shown in cumarin pulsed dye laser and Nd:YAG laser in animal experiments.[13-15]

We report herein our initial clinical experience in 16 patients with difficult common bile duct stones which could not be treated successfully by other conventional methods. All patients were treated by a pulsed rhodamine-6G dye laser with an integrated automatic stone-tissue detection system (STDS) using ERCP under radiologic control.

Materials and Methods

Patients and endoscopic techniques

From October 1997 to August 1998, a total of 16 patients (9 females and 7 males) were treated by endoscopic laser lithotripsy via the retrograde route. The technique used was laser fragmentation under plain fluoroscopic control. The mean age of patients was 60.7±14.8 years (range 32 to 83 years). Eight of the 16 patients (50%) had previously undergone cholecystectomy, whereas 6 patients (37.5%) in conjunction with choledochotomy. Eleven of 16 patients (68.8%) were referred to us from other hospitals. In one case, laser fragmentation was performed via the opening of choledochoduodenostomy from previous surgery. Antibiotic therapy had been started by the referring hospitals or on admission in case of acute cholangitis. In patients with mild cholangitis or dramatically response to antibiotic therapy (4 cases), ERCP with laser lithotripsy were performed in the first endoscopic treatment. If severe acute cholangitis was present, temporary endoscopic biliary drainage by plastic stent (4 cases) was placed in common bile duct. When septic processes subsided, usually about one week, the endoscopic laser lithotripsy was then performed in the second session.

ERCP was performed under sequential intravenous sedation and spasmolytic agents, i.e. 2.5-5.0 mg of midazolam and 2-6 ml of butylscopolamine. If necessary, 0.9 gm of lysine acetylsalicylate was given additionally for analgesia. Standard sphincterotomy was done in every cases. The estimation of stone size was determined during ERCP (on fluoroscopy) and after each treatment session by analysis of all x-ray films.

All patients had ERCP performed by a standard duodenoscope under radiologic control only ("blind" fragmentation technique). The laser fiber was already positioned into the delivery triple lumen balloon catheter (#5047 Microvasive, Boston-Scientific Corporation) before passing up in the common bile duct, with the tip of the laser fiber 3-5 mm protuded out from the catheter tip for fragmentation. The position of the fiber related to the catheter was marked at outer end of the catheter for proper length control to prevent its slipping during treatment. When we inserted the prepared catheter through the scope, before cannulation into the common bile duct, the laser fiber was again checked for appropriate position (3-5 mm out of the catheter tip). The position of catheter/laser fiber system should be adjusted until the tip of the fiber was in close contact with the stone as easily seen under fluoroscopy when we inflated the balloon with 2-3 ml of air. A solution of 1:1 to 2:1 saline / contrast medium was rinsed via the catheter intermittently during laser treatment. Because we used the balloon blockage technique, the saline/contrast medium solution usually maintain in the common bile duct for a longer period of time, so we needed not to continuously drip the solution (Figure 2). The number of administered energy pulses was limited by the degree of stone fragmentation fluoroscopicallly, by patient's pain tolerance and finally by the amount of time needed. If the treatment session took long time (more than 90 minutes) or when the patients could not tolerate the procedure, the treatment was terminated and a sec-

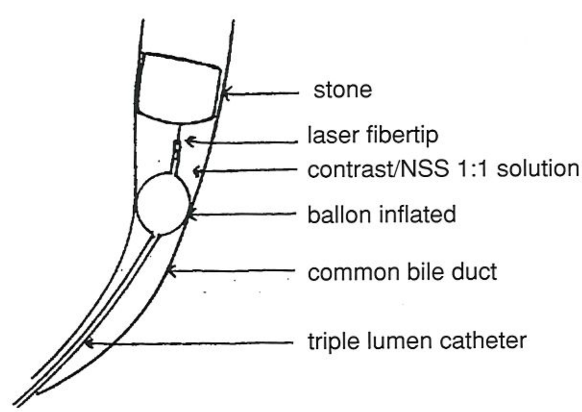

Fig. 1 Position of the fiber during treatment.

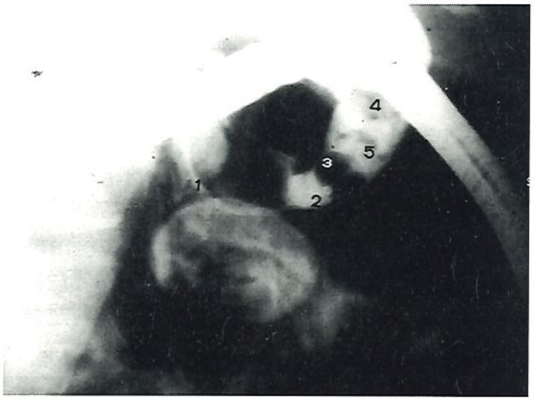

Fig. 2 Fluoroscopic view during laser lithotripsy
(1 = triple lumen catheter with laser fiber inside, 2 = CBD filled with contrast, 3 = air inflated balloon, 4 = stone, 5 = some fragments of stone)

Table 1 Diagnosis of the patients before laser treatments.

Diagnosis	n	%
Retained CBD-stone	3	18.8
Recurrent CBD - stone	4	25.0
Gallstone with CBD-stone	2	12.5
CBD-stone	5	31.2
Impacted papilla stone	2	12.5
Total	**16**	**100.0**

ond session was scheduled about one week later. The fragmented stones were removed by standard instruments, i.e. basket and balloon.

Laser and STDS (electronic system for automatic stone/ tissue discrimination)[16]

A flash-lamp pulsed dye laser (Lithognost, Telemit Corp; Munich, Germany) with a rhodamine-6G dye was used. An emission wavelength of 595 nm in the orange red region of the optical spectrum was applied with a pulse duration 2.5 μs. The pulse energy could be tuned from 40 to 120 mJ in steps of 5 mJ. Before laser lithotripsy, the pulse energy was measured at the distal fiber end by an internal power meter and the selected pulse energy automatically adjusted by the laser system. The pulses energies between 80-120 mJ (at the distal fiber end) were used. As a standard procedure, treatment proceeded with a pulse energy of 80 mJ per pulse. The energy setting was increased in two steps up to a maximum of 120 mJ, depending on the achieved fragmentation effect. The pulse frequency was varied between 1 and 10 Hz in steps of 1 Hz. Usually, lithotripsy was performed at a repetition rate of 5-8 Hz. A quartz step index fiber with a core diameter of 250 μm (outer diameter 0.5 mm) was applied in all cases.

The STDS system can be differentiated the stone from other tissues. Laser pulse will cut off at maximum 5-8 per cent of energy set when the target is not stone. The safety and effectiveness were confirmed by previous studies.[17,18]

Statistical analyses

In case of normal population distribution the results were presented in mean ± SD, otherwise were presented in median and range.

RESULTS

The laser energies were released by using 80-120 mJ and 5-8 Hz frequency as described above. Laser lithotripsy and bile duct clearance was achieved in 14 of 16 patients (87.5%). In the first failure case, the size of stone was 4.0 cm and he underwent laparoscopic cholecystectomy with duct exploration and removal of the stone. The second failure case, the stone size was 3.9 cm and she had previous 3 sessions of endoscopic mechanical lithotripsy. The laser treatment was applied in the 4th session but failed to fragment the stone. Furthermore, in the 5th session, mechanical lithotripter wire was broken during treatment resulted in impaction of stone and the basket. Finally, this patient was treated by open surgery with uneventful results.

The mean size of stones was 2.7 ± 1.0 cm, ranging

Table 2 Previous operations of the patients.

Previous operations	n	%
No previous operation	7	43.8
Explor-lap (trauma)	1	6.3
O.C. with choledochoduodenostomy	1	6.3
L.C.	2	12.5
O.C. with CBD-exploration and previous T-tube placement	4	25.0
O.C. with remain T-tube	1	6.3

O.C. = Open cholecystectomy, L.C.= Laparoscopic cholecystectomy

Table 3 Results of 16 patients treated by laser lithotripsy.

Patients age (yr)	60.7±14.9 (32-83)
Number of stones larger than 1 cm, Mean ± SD (range)	1.4±1.0 (1-5)
Stone size (cm), Mean ± SD (range)	2.7±1.0 (1.5-4.5)
Number of all endoscopic treatment sessions/patient, Median (range)	1 (1-6)
Number of laser treatment sessions/patient	1
Total number of pulses/patient, Mean ± SD (range)	2849±4400(278-18743)
Number of correct pulses/session, Mean ± SD (range)	1658±2645 (8-11224)
Number of "misapplied pulses", Mean ± SD (range)	1194±1878 (25-7519)
Stone-free patients (n) (%)	14/16 (87.5)

from 1.5 to 4.5 cm. There were 7 new cases (43.8%) while 9 cases (56.2%) had previous abdominal operations and 6 cases of this (37.5%) had choledochotomy. The lowest number of pulses that could fragment the stone were only 8 which the stone was impacted at the ampulla and easily to performed the treatment. The highest number of pulse applied was 11224 in a patient who had two common bile duct stones size 2 cm each. No serious complication was observed. The 30-day mortality rate was 0%.

Discussion

The first paper of laser lithotripsy by endoscopic retrograde technique for treatment of CBD stones by Nd:YAG laser was reported in 1986. In this report they found that Nd: YAG laser was better for pigmented stone than cholesterol stone.[19] Another report using flashlamp-pumped tunable dye laser also confirmed that cholesterol stones had distinctly higher thresholds than pigmented stones. The reason because dark-colored pigmented stones are better absorbers of visible light than light-colored cholesterol stones.[20] In our study, a complete bile duct clearance was achieved in 14 of 16 cases (87.5%). Ponchon reported complete stone clearance in 5 of 14 patients[12] but Ell reported a higher success rate of stone clearance in 8 of 9 patients.[16] Ponchon used flash lamp pulsed dye laser without stone recognition system and stated that the "tick-tick" signal generated during correct position of laser fiber application to the stone was not sufficient criterion for ensuring the safety of "blind" technique. This explained the low success rate of only 5 of 14 patients (35.7%) under fluoroscopic control in his study. But in Ell experiences, using the stone-tissue detection system (STDS), as in this study, the success rate was up to 8 of 9 patients (88.9%). The unique feature of this electronic system is the following : the measurement serving to ensure proper contact of the stone with the fiber can be performed within 0.2 μs. Thus the relatively long laser pulse (~ 2.5 μs) can be interrupted immediately if no stone is detected by fast photodiode[16]. So with this special detection action, high level of safety was proved both in vitro[18] and in animal experiments.[17] Because the tip of laser fiber should be in closed contact with the target stone, this sometimes may be a problem due to the non-radiopaque of the fiber itself. To solve this problem, we had two choices, using catheter with radiopaque at its tip or balloon catheters.[12,16] We found that the triple lumen balloon catheter as described above in our series helped to solve some technical problems. With the aid of the inflated balloon, we could clearly see the tip of the catheter by fluoroscopy so that we were able to adjust the fiber into close contact with the stone. Another advantages are: the balloon helps to stabilize the tip of laser fiber in the central of the duct lumen and requines only intermittent saline contrast solution rinse instead of continuously drip as previous study.[16] During lithotripsy, if the catheter/fiber system is pushed too much it will kink or bend and result in tangential instead of perpendicular contact, there by limiting the efficacy of the laser power.

In fact, STDS laser lithotripsy under fluoroscopic control is safe and effective although the number of misapplied laser pulses may be higher than direct vision via a "baby" endoscope system.[11,12,16,21] The main problem during laser fragmentation is the exact position of the laser fiber tip due to its non-radiopaque. The solutions may be in two ways : coating the laser fiber with the radiopaque material or using a direct visual control under "mother/baby" endoscopic system. However, gold coating of the fiber, as one possibility of achieving radiodensity, makes the fiber fragile in most cases and is unsatisfactory at the movement.[16]

Other techniques used in fragmentation of the CBD-stone are extracorporeal shockwave lithotripsy and intracorporeal electrohydraulic lithotripsy. In case of extracorporeal lithotripsy, which has been shown to be efficacious and safe,[22] the major draw back is the need for a three stages approach (nasobiliary drain insertion, lithotripsy, and fragment extraction) which makes this method time consuming.[12] The intracorporeal electrohydraulic lithotripsy, which main advantage is the lower cost of the instrument, also proved efficacious in expert hands.[23-26] But this technique also time consuming and invasive because it should be used under direct endoscopic visualization to avoid injury to the ductal wall. In a canine model, only one electrohydraulic shock applied to the common bile duct wall may produce bleeding and even perforation.[27]

In conclusions, endoscopic laser lithotripsy under radiologic control by using an automatic stone recognition system for difficult bile duct stone that fails in conventional method is safe and effective, especially in the elderly or cholecystectomized patients. However, further study of a larger series to assess the true benefit of this new method is necessary. This primary data indicated to us a very promising results.

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