Laser lithotripsy of difficult bile duct stones under direct visual control

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Abstract
Biliary laser lithotripsy was performed under direct visual control in 35 consecutive patients not amenable to routine endoscopy. The patients had 1–50 (median 1) bile duct stones with the greatest diameter of the largest stone being 9–42 mm (median 20 mm). Conventional endoscopic treatment had failed because of an inaccessible papilla (16 patients), biliary strictures (seven patients), and impaction or large size of calculi (12 patients). Twelve patients, depending on their anatomical condition, underwent peroral cholangioscopy by means of a mother-baby scope. Percutaneous cholangioscopy was initially carried out in 23 patients, 7–20 days (median 10 days) after creation of a transhepatic fistula. Pulsed dye laser (32 patients) or alexandrite laser (three patients) lithotripsy was applied under an appropriate direct visual control in all cases. Complete stone disintegration succeeded in 33 of 35 patients. All resultant fragments passed the papilla within a median number of 1–3 treatment sessions. Peroral cholangioscopic lithotripsy failed in two cases. One patient successfully underwent percutaneous laser treatment and the other patient was referred to surgery. Fever, temporary haemobilia, or a subcapsular liver haematoma were seen in a total of eight patients during establishment of the cutaneous biliary fistula. A 95-year-old patient who had been admitted with septic cholangitis died because of cardiorespiratory failure 5 days after bile duct clearance. It is concluded that laser lithotripsy performed under a direct visual control is an effective and safe procedure for the non-surgical treatment of difficult bile duct stones. Ductal clearance can usually be achieved in a single treatment session when the papilla and the stones are accessible by the peroral route. Percutaneous cholangioscopic lithotripsy is more time consuming but highly effective even in patients with a difficult anatomy, bile duct strictures, or intrahepatic calculi. This approach should be limited, however, to cases not amenable to retrograde procedures because the creation of the cutaneous biliary fistula is not without risks. (Gut 1993; 34: 415–421)

Endoscopic papillotomy has become an established method of treating bile duct stones in patients with previous cholecystectomy and in elderly or high risk patients with the gall bladder in situ. The procedure cannot be performed when the papilla is retrogradely inaccessible because of anatomical abnormalities of the duodenum or previous, full-thickness bile duct surgery. In addition, stone removal or mechanical lithotripsy fails in about 5% of the patients because the calculi are too large, impacted, or located above biliary strictures. For this selected group of patients intraductal litholysis, extracorporeal and various intracorporeal lithotripsy procedures under fluoroscopic or endoscopic guidance were proposed. Pulsed dye laser lithotripsy is one of the most promising methods for achievement of a safe and rapid bile duct clearance. A major problem of this technique consists in transmission of the laser energy to ductal stones. A prospective trial was performed to study the application, efficacy, and side effects of pulsed dye laser or alexandrite laser lithotripsy performed under a direct visual control in a consecutive series of patients with bile duct stones not amenable to conventional endoscopy.

Patients
Between July 1990 and November 1991, 35 of 38 patients referred for non-surgical treatment of bile duct stones after failure of conventional endoscopy were selected for laser treatment (Table). In elderly patients or high risk patients with the gall bladder in situ no subsequent cholecystectomy was planned. Three patients were excluded from the study group because they were less than 70 years with no concomitant diseases and had gall bladder stones together with bile duct calculi. These patients underwent cholecystectomy and common bile duct exploration.

Characteristics of stones had been determined by endoscopic retrograde cholangiography.
(ERC) in 19 patients in whom the papilla of Vater could be approached by the peroral route. Removal of the calculi and mechanical lithotripsy had failed in all of these cases even after endoscopic papillotomy (EPT). Extracorporeal shock wave lithotripsy had been unsuccessful in one patient with a prepapillary common bile duct stone. A peripapillary oedema because of retro-duodenal perforation after EPT prevented further peroral procedures in another patient. In another 15 patients with a retrogradely inaccessible papilla suspected bile duct stones were confirmed by percutaneous transhepatic cholangiography (PTC).

The patients were allocated for cholangioscopic laser lithotripsy by the peroral route when the papilla was accessible and there were no bile duct strictures downstream of stones which would prevent insertion of a baby cholangioscope. A percutaneous approach was planned in patients who had no retrograde access to the papilla, stones above bile duct strictures, or failure of peroral lithotripsy or a combination of these three reasons (Table, Fig 1).

**Methods**

All endoscopic and percutaneous procedures were carried out under sedation with 2.5–7.5 mg midazolam given intravenously. If necessary, 25–100 mg pethidin-HCl was given additionally for analgesia. Antibiotics were not given prophylactically.

**PERORAL CHOLANGIOSCOPY**

A probe was endoscopically inserted immediately before cholangioscopy to allow flushing down of fragments during lithotripsy for patients without a nasobiliary drain. Cholangioscopy was carried out by means of a mother-babyscope system (TJF-M20 and CHF-B20, Olympus Optical, Tokyo) or a prototype cholangioscope with an outer diameter of 3.4 mm (Olympus) which was inserted through the 4.2 mm instrumentation channel of a standard duodenoscope (TJF10; Olympus) (Fig 2A). During treatment, irrigation was performed by manual injection of saline through a 3-port Luer-Lock stop cock attached to the proximal end of the babyscope.
working channel to improve the contact of the laser fibre with the stone surface and to clear the lens of the endoscope.

**PERCUTANEOUS CHOLANGIOSCOPY**

After visualisation of the stones by PTC a 10 French gauge (FG) catheter was inserted into the biliary system through the right lateral chest wall in 19 patients. The probe was introduced through the anterior abdominal wall in four patients with strictures of the left hepatic duct. A transpapillary placement of the pigtail shaped tip of the catheter was attempted at the same time. The cutaneobiliary fistula was dilated in one to three further sessions depending on the rigidity of stenoses and the anatomical situation by replacing the percutaneous catheters with increasing diameters every second or third day. The final diameter of the sinus tract was 14 FG, 16 FG, 18 FG, and 20 FG in three, 13, six, and two patients, respectively. The large bore fistulas were made for an appropriate dilatation of biliary strictures. One to 3 weeks after initial PTC the drainage catheters were removed and a standard cholangioscope (CHF P10 or P20, Olympus) or a

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Figure 3: (A) Endoscopic retrograde cholangiography shows a 40 mm bile duct stone above a biliary stricture after previous cholecystectomy in an 83 year old patient. (B) Cholangiography shows transhepatic insertion of a cholangioscope after creation of a cutaneobiliary fistula and percutaneous dilatation of the stenosis. (C) Approach of a 200 cm laser fibre with a helium aiming beam to the surface of the stone under direct visual control. (D) Disintegration of the calculus during pulsed dye laser lithotripsy. (E) Cholangioscopy shows a surgical thread within the fragmented stone. (F) Clear bile duct above the dilated biliary stricture after discharge of 1000 laser pulses and prograde removal of the fragments through the papilla within the same session. (G) Cholangioscopic cholangiography shows a clear biliary tree. (H) Collected fragments in faeces of the patient; further disintegration of the larger particles had not been intended because of a smooth transpapillary passage.
prototype 3.7 mm cholangioscope (Olympus) was inserted into the biliary system through the firm transhepatic fistula under direct visual control without the need for guide wires or sheaths (Fig 1A and B). In contrast with the longer babyscopes, irrigation could be achieved by the cholangioscope with less pressure by means of a saline infusion connected to the instrumentation channel.

**LITHOTRIPSY**

A flashlamp excited dye laser with a wavelength of 504 nm (MDL 2000, Candela, Boston, MA) was used in 32 patients. The 1 μs laser pulses were applied at a repetition rate of 4–6 Hz and an energy output of 40–60 mJ. If stones fragmented too slowly the energy was increased to 100 mJ provided that targeting of the calculus could be optimally achieved. An alexandrite solid state laser system (HMT Alexandritor, High Medical Technologies, Kreuzlingen, Switzerland) with a pulse duration of about 500 ns and a peak power density of 1 8 MW/mm² was applied at a wavelength of 750 nm, a repetition rate of 10 Hz, and an energy output of 60 mJ in three patients. For both laser systems the energy was transmitted by a 200 μm or a 320 μm flexible quartz fibre. The placement of the tip of the probe to the surface of the stone was helped by a helical aiming beam. Shocks were applied until the stones disintegrated into fragments which seemed appropriate for passage into the duodenum or jejunum, respectively. There was no upper limit on the number of pulses, but lithotripsy was discontinued when no clear image of stone targeting could be achieved. Complete clearance of the biliary system was attempted at the same time by irrigation through the instrumentation channel of the endoscope and the nasobiliary probe. Particles which did not spontaneously pass the papilla were exchanged retrogradely with basket catheters after peroral cholangioscopy or they were pragradely pushed through the papilla or a biliodigestive anastomosis with the percutaneously inserted cholangioscopes. When bile duct clearance could be achieved no further percutaneous drainage catheter was inserted. In three patients with tight and rigid bile duct strictures, PTC catheters occluded at the skin level were left in situ for internal drainage over a period of 3–6 months to prevent early biliary restenoses. On the day of lithotripsy and on the day after, all patients had a physical examination and laboratory tests, including a complete blood count, aspartate aminotransferase, alanine aminotransferase, γ-glutamyltransferase and pancreas enzymes were carried out.

**Results**

**PERORAL CHOLANGIOSCOPIC LITHOTRIPSY**

Lithotripsy and bile duct clearance was achieved in 10 of 12 patients within a single treatment session after application of 270, 370, 460, 550, 580, 690, 760, 1000, 1800, and 2800 pulses, respectively (Fig 2). Stone fragmentation was not achieved because of inappropriate irrigation in one patient who had an impacted prepyloric calculus which had been refractory to extracorporeal shockwave lithotripsy previously performed. This concern was later treated by the percutaneous route. In another patient, partial disintegration of a 42 mm stone at the cystic duct confluence was obtained but large inaccessible portions of the calculus were impacted in the cystic duct and caused compression of the common bile duct. This patient successfully underwent surgery. There were no complications in this group of patients (Fig 1).

**ESTABLISHMENT OF A CUTANEOBILIARY FISTULA**

PTC was successful in all 23 patients who were initially selected for the percutaneous approach and in one patient after failure of peroral lithotripsy. In 22 cases a 10 FG pigtail catheter was inserted percutaneously through the biliary tract by the papilla or biliodigestive anastomosis within the same session. In two patients establishment of this cutaneous drainage route required a second procedure after temporary intrahepatic positioning of the catheter. A mean of 1.5 (range 1–3) subsequent dilatation sessions were needed for the creation of the cutaneobiliary fistula. Fever occurred in three patients with intrahepatic stones after placement of the percutaneous catheter. During the percutaneous drainage procedures, haemobilia because of temporary biliovenous fistulas or a subcapsular liver haemotoma was seen in four patients and one patient, respectively. All of these complications were successfully managed by conservative measures.

**PERCUTANEOUS CHOLANGIOSCOPIC LITHOTRIPSY**

Percutaneous cholangioscopy was carried out 7–20 days (median 10 days) after initial insertion of a percutaneous catheter. In all 24 patients the bile duct stones could be approached. A median number of 530 pulses of the dye laser system were applied in 21 patients under direct visual control (20, 50, 90, 120, 160, 160, 280, 360, 390, 460, 530, 760, 980, 1030, 1100, 1780, 2000, 2800, 3100, 5460, and 10 300 shocks per case, respectively). Alexandrite laser lithotripsy was performed in three patients with discharge of 2410, 4550, and 11 300 shocks, respectively. Complete stone disintegration was achieved in all cases. The size of the resultant stone particles could be reduced to a diameter of 1–3 mm. Lithotripsy was discontinued earlier, depending on the individual anatomical situation, when the size of the largest fragment seemed appropriate for a passage into the duodenum or jejunum. Bile duct clearance was accomplished in 23 of 24 patients after a mean of 1.3 (range 1–3) treatment sessions (Figs 3 and 4). In one patient with a stricture of the left hepatic duct, a giant stone mass at the hilum, and approximately 50 intrahepatic calculi, the bifurcation became completely patent after lithotripsy. Some of the smaller stones, however, in peripheral segments of the right liver lobe could not be removed by means of flushing through the cholangioscope. The asymptomatic patient was discharged with a percutaneous transhepatic catheter to allow for cholangioscopic control in 8 weeks. In 23 of 24
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Discussion

The present results indicate that laser lithotripsy under cholangioscopic guidance is a safe and effective treatment in patients with difficult bile duct stones not amenable to conventional endoscopy. In a consecutive series patients were only excluded when cholecystectomy was indicated together with treatment of ductal calculi because there was no clear benefit for combined endoscopic and surgical approach in young and fit patients.10-12 This approach seems to be even less useful when the non-surgical treatment is particularly difficult. In all 12 patients with an adequate peroral approach to the papilla the stones could be directly visualised before and during lithotripsy by means of a mother-baby-scope system. Limitation of vision because of the resultant fragments, as previously reported, was avoided by saline irrigation through the instrumentation channel of the babiescope next to the laser fibre.13 This technique additionally improves stone fragmentation which is more effective under fluid.14-16 Irrigation was insufficient for effective lithotripsy of a prepyloric stone which had been refractory to extracorporeally applied shockwaves previously. This patient received percutaneous cholangioscopic lithotripsy and subsequent stone disintegration with the same laser energy showed that a precise energy transmission is predominantly important for efficacy. Peroral cholangioscopic lithotripsy failed in another patient with an impacted stone at the cystic duct confluence. In 10 of 12 patients complete bile duct clearance was obtained in a single treatment session. In addition to the patient with failed peroral cholangioscopic lithotripsy, 23 patients who were not amenable to retrograde techniques initially received percutaneous laser treatment. This selection was mainly because of specific referral from other hospitals. In all these patients a percutaneous transhepatic approach seemed to be the only alternative to surgery. In 16 cases the papilla of Vater was retrogradely inaccessible mainly because of a difficult anatomy after previous gastroduodenal or biliary surgery. Seven patients received percutaneous treatment of stones above difficult bile duct strictures not amenable to conventional endoscopy. The establishment of a cutaneous fistula appropriate for the insertion of cholangioscopes required a mean of 2-6 percutaneous procedures for each patient. Lithotripsy was performed on average 10 days after initial percutaneous transhepatic cholangiography. This period proved to be appropriate for cholangioscopy provided that the endoscopes are inserted carefully and no stones or fragments are extracted through the fistula. Creation of a sinus tract over 3 or 4 weeks as
proposed from Japanese groups was not required for this group of patients. More time may be saved but this was not possible in the trial because of a busy schedule of other daily endoscopies.

Creation of a fistula and cholangioscopy within a single session, as previously reported, was not attempted because rapid dilatation is painful and frequently caused severe bleedings in other trials. In addition, drainage catheters must be left in situ to avoid biliary leakage and so little time is saved. The complications resulting from drainage procedures seen in eight of 24 patients were conservatively managed. These side effects, however, indicate that the percutaneous technique should be limited to patients with stones not amenable to retrograde methods. After creation of the fistula cholangioscopic lithotripsy could be safely performed and achieved complete bile duct clearance in all but one patient after a mean of 1-3 treatment sessions. Some peripheral intraductal stones could not be removed in one patient but the hepatic bifurcation became clear after lithotripsy of a giant stone mass. If necessary, the size of fragments was reduced to 1-3 mm by discharge of further pulses so that a prograde passage could be achieved even in patients without previous papillotomy. No complications related to cholangioscopic lithotripsy, such as bleeding or perforation, were seen.

The efficacy of biliary dye laser lithotripsy was previously reported in experimental and clinical studies. In contrast with other studies, cholangioscopy was routinely performed to improve the transmission of laser energy. The results of previous trials suggested that fluoroscopically controlled laser lithotripsy is less effective than the cholangioscopic approach because of several technical problems such as precise positioning of the fibre. For these reasons a direct visual control seems to be necessary even if the safety of laser systems can be further increased.

In contrast with a dye laser, the alexandrite laser theoretically offers advantages because a solid state laser is more reliable and needs no maintenance. This system proved to be even less traumatic than a pulsed dye laser or a free running mode Neodym YAG laser in an experimental trial. To our knowledge this system was clinically applied for the first time in three of the 35 patients with bile duct stones. According to these preliminary experiences lithotripsy was effective but seems to require more pulses than the pulsed dye laser at the same energy level. Cholesterol stones were more difficult to disintegrate. These experiences are consistent with results of an experimental trial. Fragmentation and shortening of the fibre during lithotripsy as recently reported was not seen with the laser used in this trial. Electrohydraulic lithotripsy is a cheap and effective alternative to laser application. There is a significant risk, however, of bile duct damage especially when performed under inadequate visual control. In addition, compared with ultrathin laser fibres, even the thinnest electrohydraulic probes are less appropriate for minisscopes, which can simplify the procedure and may reduce the risk of transhepatic dilatation. Contact is not required with difficult bile duct stones for performance of extracorporeal shockwave lithotripsy. The success rates vary between 61 and 86% after a mean of 1-2-3 procedures in larger trials. Major complications are rare but haemobilia, macrohaematuria, and haematoma of the liver or the kidney were reported. A considerable drawback of extracorporeal shockwave lithotripsy of bile duct calculi by decompression of fragments is frequently too large for spontaneous passage and require further endoscopic treatment. A percutaneous transhepatic approach, like intracorporeal techniques, cannot usually be avoided in patients with an inaccessible papilla or difficult bile duct strictures. In conclusion, cholangioscopic laser lithotripsy offers a safe and efficacious alternative to surgery for the management of patients with difficult bile duct stones. Where an adequate endoscopic approach to the papilla treatment by the peroral route is taken bile duct clearance is frequently achieved within a single treatment session. Percutaneous extracorporeal time consuming but highly successful even in patients with a difficult anatomy, bile duct strictures, or intrahepatic calculi. The creation of a cutaneobiiliary fistula can be hazardous, however, and should be limited to patients with stones not amenable to peroral procedures. Further improvements of this technique can be expected in view of the development of even safer laser systems and miniature endoscopes.
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