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RAPID COMMUNICATION

Clinical usefulness of transpapillary removal of common bile duct stones by frequency doubled double pulse Nd:YAG laser

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Abstract

AIM: To study the efficacy and the safety of laser lithotripsy without direct visual control by using a balloon catheter in patients with bile duct stones that could not be extracted by standard technique.

METHODS: The seventeen patients (7 male and 10 female; mean age 67.8 years) with difficult common bile duct (CBD) stones were not amenable for conventional endoscopic maneuvers such as sphincterotomy and mechanical lithotripsy were included in this study. Laser wavelengths of 532 nm and 1064 nm as a double pulse were applied with pulse energy of 120 mJ. The laser fiber was advanced under fluoroscopic control through the ERCP balloon catheter. Laser lithotripsy was continued until the fragment size seemed to be less than 10 mm. Endoscopic extraction of the stones and fragments was performed with the use of the Dormia basket and balloon catheter.

RESULTS: Bile duct clearance was achieved in 15 of 17 patients (88%). The mean number of treatment sessions was 1.7 ± 0.6. Endoscopic stone removal could not be achieved in 2 patients (7%). Adverse effects were noted in three patients (hemobilia, pancreatitis, and cholangitis).

CONCLUSION: The Frequency Doubled Double Pulse Nd:YAG (FREDDY) laser may be an effective and safe technique in treatment of difficult bile duct stones.

Key words: Bile duct stones; Frequency doubled double pulse Nd:YAG laser; Transpapillary removal; Mechanical lithotripsy; Balloon catheter

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INTRODUCTION

About 90% of all patients with common bile duct stones are currently treated non-surgically using endoscopic sphincterotomy and stone extraction. However, standard endoscopic procedure and mechanical lithotripsy for removal of stones from the bile duct fail in 5% to 10% of patients, because the stones are too large or impacted[1]. In such cases, additional methods such as extracorporeal shockwave lithotripsy (ESWL), laser shockwave lithotripsy (LSWL) or electrohydraulic lithotripsy (EHL) are required[2]. EHL and LSWL need visual control *via* a mother-baby endoscope system or cholangioscopy for safety because of the potential for accidental damage to the bile duct wall. Moreover, a peroral cholangioscope is expensive, fragile and difficult to use. Laser lithotripsy is expensive due to the cost of the cumbersome endoscopic equipment. Although EHL is inexpensive, it uses high-pulse energy to disintegrate stones[3-5].

The Frequency Doubled Double Pulse Nd:YAG (FREDDY) laser (World of Medicine, Berlin, Germany) is a newly developed economical, short-pulse, double frequency, solid-state laser with wavelengths of 532 nm and 1064 nm that cause less tissue damage. It was specifically designed to fragment urinary and biliary calculi[6]. We used a balloon catheter for FREDDY laser lithotripsy (FREDDY LL) in an effort to improve fluoroscopic targeting and to prevent damage to the bile duct. The purpose of this study was to investigate the safety and the effectiveness of using a FREDDY laser to treat bile duct stones that were not amendable to conventional endoscopic therapy.

MATERIALS AND METHODS

Patients

Seventeen patients (7 male and 10 female; mean age 67.8 years, range 55-82 years) with extra-hepatic bile duct

stones were included in this study. The inclusion criterion for this study was extrahepatic bile duct stones that were not amenable to standard endoscopic procedure including endoscopic sphincterotomy and mechanical lithotripsy. Stone removal by using conventional methods failed because the stones were not captured in the basket for mechanical lithotripsy or endoscopic sphincterotomy inadequately was done for large periampullary diverticulum with large CBD stones (> 1.5 cm). The main reasons were the following; large stone (n = 7), impacted stone (n = 3), and large stones with periampullary diverticulum (n = 7).

All patients were diagnosed as having bile duct stones by endoscopic retrograde cholangiography and/or MRCP at our hospital. The data regarding stone size, number, and location was based on the endoscopic retrograde cholangiogram (by using the diameter of the distal end of standard duodenosocpy as a reference). The properties of the CBD stones were as follows: 1 stone (n = 5), 2 stones (n = 7) and more than 2 stones (n = 5); diameter of large stone (18.5 ± 3.2 mm) with 10-20 mm (n = 8) and with 21-30 mm (n = 9). Large stones with periampullary diverticulum were found in 11 of 17 patients. The study was approved by our institutional review board. Written informed consent was obtained from each patient for laser therapy.

Methods

we used the FREDDY laser (frequency doubled double pulse Nd:YAG laser, Laser 100, World of Medicine). Laser wavelengths of 532 nm and 1064 nm as a double pulse were applied with pulse energy of 120 mJ. The laser fiber with a 250 nm core diameter was inserted in a 6.8 Fr standard extraction balloon catheter (Wilson-Cook Medical Inc., Winston-Salem, N.C.) with an 18-mm-diameter balloon and this was then passed through the papilla *via* the working channel of a standard duodenoscope (JF-240; Olympus Optical Co., Ltd. Tokyo, Japan).

As the fiber itself is not detectable by fluoroscopy, the radio-opaque tip of the balloon catheter was positioned near the stone, and the balloon was expanded to fix the position of the catheter and the fiber. The tip of the fiber was advanced a few millimeters beyond the radio-opaque tip of the balloon catheter, under fluoroscopic guidance, to ensure that the fiber was positioned on the stone surface. Only one fluoroscopic plane was used to target the stone and to observe fragmentation. The treatment energy level was 120 mJ per pulse at a repetition rate of 8 to 10 Hz. During the laser treatment, we tried to listen to the fragmentation sound of stone by using stethoscope and the fragmentation effect was monitored by fluoroscopy after instillation of contrast media into the bile duct. During laser lithotripsy, the bile duct was continuously irrigated with a mixture of contrast media and saline solution because fluid is required for the generation of shock waves.

After stone disintegration, endoscopic extraction of stones and fragments was done with a dormia basket and balloon catheter. Laser lithotripsy was limited to a maximum duration of 60 min per session. If, at that time, the ductal clearance was incomplete, then a nasobiliary catheter was inserted. Failure of laser lithotripsy was defined as the inability to achieve complete bile duct clearance after a maximum of three lithotripsy sessions.

All patients were followed for at least two days after the FREDDY LL. Follow-up included simple radiographs and laboratory tests (hemoglobin, white blood cell count, bilirubin, alanine aminotransferase, aspartate aminotransferase, creatinine, serum urea nitrogen, amylase and lipase levels). The occurrence of any complication within one month of the FREDDY LL procedure was assessed by a patient visit or telephone interview.

RESULTS

Lithotripsy

Complete stone fragmentation using FREDDY LL was achieved in 15 of 17 patients without direct visual control (Figure 1). The number of endoscopic retrograde cholangiography sessions per patient that was necessary to totally clear the bile ducts was 1.7 ± 0.6. After FREDDY LL, 3 patients underwent mechanical lithotripsy to achieve complete clearance of the bile duct.

The stone fragmentation failed in two patients, in whom the positioning of the laser fiber on the stone was inadequate due to a huge impacted stone in the tortuous common bile duct and the biliary stricture. One patient was sent to the surgical department to clear the bile duct by laparoscopic surgery. The other patient was treated by percutaneous cholangioscopy with electro-hydraulic lithotripsy.

Complications

The side effects and complications of FREDDY LL were mostly mild. Although acute pancreatitis occurred in one patient, it was treated by conservative management, and there was no pseudocyst. Transient hemobilia was observed in two patients. However, the bleeding stopped spontaneously without any change of the hemoglobin level. The hemobilia may have been caused by mucosal damage from insertion of the guiding catheter or the balloon catheter. A patient with acute cholangitis was treated by administration of antibiotics and nasobiliary tube irrigation. This complication may have been caused by transient obstruction of the nasobiliary tube.

DISCUSSION

Endoscopic retrograde cholangiopancreatography (ERCP) and sphincterotomy have been the standard treatments for choledocholithiasis, yet large stones present a major challenge for the endoscopist. Extending a sphincterotomy increases the risk of bleeding and perforation, and mechanical lithotripters are generally expensive, cumbersome to use, and fragile, and they fail to grasp the stones in a significant number of cases. For treating these patients, the complementary techniques such as extracorporeal shock wave, intracorporeal electrohydraulic, or laser induced lithotripsy are required[2].

Electrohydraulic intracorporeal lithotripsy (EHL) represents an effective treatment option for the endoscopic treatment of difficult bile duct stones. However, EHL requires continuous visual control of the fragmentation procedure because of the high pulse energies that are used.

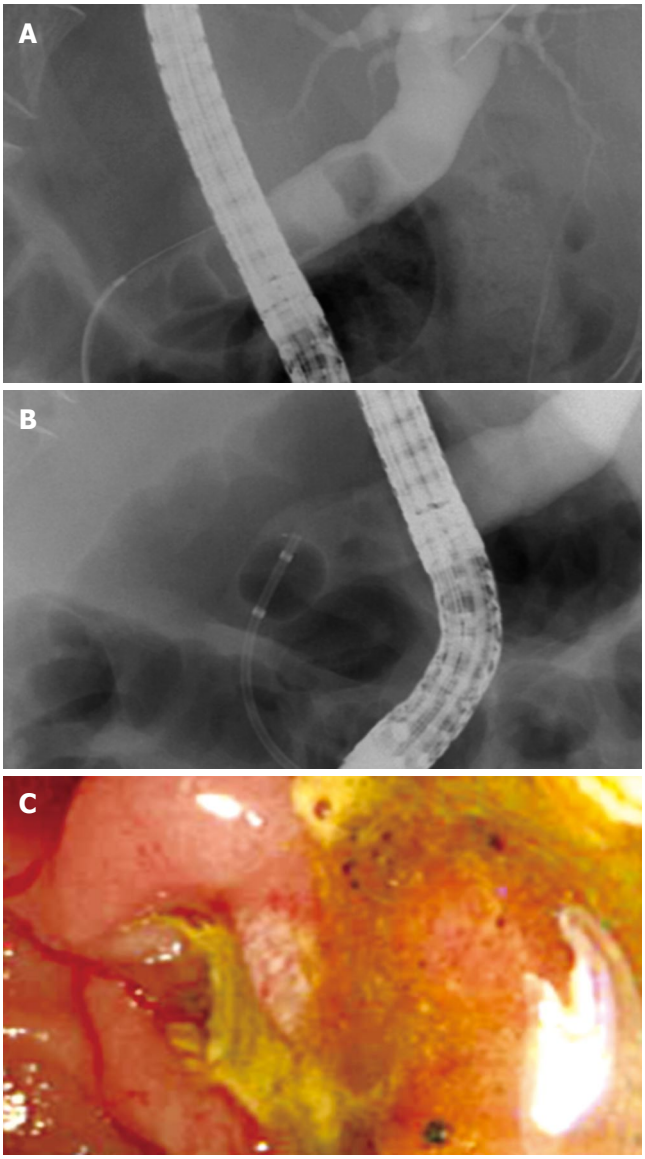

Figure 1 Complete stone fragmentation using FREDDY without direct visual control. **A**: Cholangiogram showing stone impacted in the common bile duct; **B**: Cholangiogram made during FREDDY laser lithotripsy, showing multiple stone fragments; **C**: Endoscopic findings showing the fragmented stones from the bile duct.

The probe contacting with the bile duct wall may result in perforation or bleeding. Cholangioscopy with continuous saline solution irrigation is routinely performed during EHL. Transpapillary cholangioscopy with a mother-baby endoscope requires two experienced endoscopists. In addition, this type of endoscope is so fragile, and its cost is high. Also, EHL is associated with a high level of exposure to ionizing radiation for both the patient and the endoscopist[4,5]. Data on laser lithotripsy for complicated bile duct stones have been reported by several centers. Stone fragmentation rates of about 80%-90% have been reported for the coumarin green and Nd:YAG laser under direct cholangioscopic control. When performing laser lithotripsy under fluoroscopic guidance, the method failed in up to 80% of patients, because positioning of the glass fiber on the stone was difficult. But in 1993, a flash-lamp pulsed laser with a tissue-stone recognition system was introduced that could identify gallstones by analyzing the back-scattered light and the energy pulse was interrupted in case of tissue contact. The visual control of placing the tip of the probe to the surface of the stone is facilitated by a helium-aiming beam. This system allows the treatment to be performed under fluoroscopic control with excellent safety and fragmentation success rates of up to 90%. Fluoroscopic control using a rhodamine 6G laser was effective in clearing the bile ducts in about 80% of patients[2,8].

The FREDDY laser has been developed for endoscopic lithotripsy to disintegrate urinary stones. We applied this laser on the biliary stone that was not amenable to standard endoscopic procedure including endoscopic sphincterotomy and mechanical lithotripsy through the transpapillary route. In our study, stone disintegration through the transpapillary route was achieved in 15 of 17 patients (88%). The FREDDY laser is a short pulsed Q-switched frequency-doubled, double pulse Nd:YAG solid-state laser that allows the emission of long pulses. This laser is capable of producing very high pulse intensity because of the partial frequency doubling of the infrared ray into the green range that works synergistically. Laser light at 532 nm (the green spectrum) initiates plasma formation at the stone surface, while light at a wavelength of 1064 nm heats the preformed plasma, to cause expansion and contraction, which fragments calculi, and the pulse duration is 0.5-1.5 μs[9]. This laser generates very short impulses that are poorly absorbed by soft tissue, and so the tissue is exposed to virtually no thermal effect. *In vitro* experiments show that FREDDY laser is very suitable for performing lithotripsy, and animal model studies have shown little to no effect on normal tissues[10].

Also, in comparison with the holmium laser, the FREDDY laser produces no thermal effect[11]. This laser showed a high degree of fragmentation efficiency (95%) on the urinary stone, but yet any studies of its effect on biliary stones are rare. There was an 88% fragmentation rate in our study, although the number of patient was small. The FREDDY laser system combines the advantage of solid-state and pulse-dye lasers such as lower cost, good reliability, and excellent effectiveness.

The number of ERCP sessions necessary for duct clearance was higher in our study than reported for other study groups. When laser therapy was done as the first line method for difficult cases, additional ERCP sessions were necessary to achieve complete bile duct clearance[12]. A disadvantage of the FREDDY laser system is the high x-ray exposure to patients and the endoscopist. Also, it is difficult and time consuming to target the stone by fluoroscopy because of the positioning of the laser fiber that is inserted through a balloon catheter[13]. A certain level of endoscopic technique is required to contact the balloon catheter with laser fiber on the surface of a stone. Positioning of the balloon may be unsatisfactory in a tortuous angulated bile duct like our cases that laser lithotripsy failed. To ensure that the fiber would target the stone exactly and avoid contact with the bile duct, we monitored stone movement in the bile duct, fragmentation sound by applying stethoscope and hemobilia during this laser treatment.

In conclusion, our results suggest that laser lithotripsy using FREDDY without direct visual control was an effective and safe technique for patients with difficult CBD stones that could not be removed by mechanical lithotripsy. In the future, comparative studies with EHL, ESWL, or other laser systems will be required to assess the utility and efficacy of FREDDY laser.

COMMENTS

Background

Endoscopic papillotomy is successful in more than 90% of the cases of choledocholithiasis. For patients with difficult bile duct stones not responding to mechanical lithotripsy, different methods for stone fragmentation such as laser lithotripsy or electrohydraulic lithotripsy (EHL) with direct visual control have been developed. A major problem in using this device is the requirement of cholangioscopic guidance or the "mother and baby" endoscope.

Research frontiers

Recently, a new laser, the Frequency Doubled Double Pulse Nd:YAG (FREDDY), was developed for endoscopic lithotripsy for urinary stones, and has less tissue damage. The efficacy and safety of laser lithotripsy without cholangioscopy by using the balloon catheter were evaluated in patients with bile duct stones that could not be extracted by standard technique.

Innovation and breakthroughs

The FREDDY laser is a newly developed economical, short-pulse, double frequency, solid-state laser that results in less tissue damage. Fluoroscopically guided laser lithotripsy with a balloon catheter through a peroral duodenoscope appears to be effective treatment for bile duct stones that cannot be extracted by using conventional techniques such as mechanical lithotripsy.

Applications

For the fragmentation of the biliary stone, cholangioscopy guidance is expensive due to the cost of the cumbersome endoscopic equipment and the need for two experienced endoscopists operating the "mother and baby" endoscope. When direct visual control is not available or limited, laser lithotripsy with a balloon catheter may be an alternative. To target the laser fiber accurately on the stone in the bile duct, a new and easier method is required.

Peer review

It is a well-written and interesting paper. The FREDDY laser may be a useful technique in treatment of difficult bile duct stones.

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