Outcome of simple use of mechanical lithotripsy of difficult common bile duct stones

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AIM: The usual bile duct stone may be removed by means of Dormia basket or balloon catheter, and results are quite good. However, the degree of difficulty is increased when stones are larger. Studies on the subject reported many cases where mechanical lithotripsy is combined with a second technique, e.g., electrohydraulic lithotripsy (EHL), where stones are crushed using baby-mother scope electric shock. The extracorporeal shock-wave lithotripsy (ESWL) or laser lithotripsy also yields an excellent success rate of greater than 90%. However, the equipment for these techniques are very expensive; hence we opted for the simple use of mechanical lithotripsy and evaluated its performance.

METHODS: During the period from August 1996 to December 2002, Mackay Memorial Hospital treated 304 patients suffering from difficult bile duct stones (stone >1.5 cm or stones that could not be removed by the ordinary Dormia basket or balloon catheter). These patients underwent endoscopic papillotomy (EPT) procedure, and stones were removed by means of the Olympus BML-4Q lithotripsy. A follow-up was conducted on the post-treatment conditions and complications of the patients.

RESULTS: Out of the 304 patients, bile duct stones were successfully removed from 272 patients, a success rate of about 90%. The procedure failed in 32 patients, for whom surgery was needed. Out of the 272 successfully treated patients, 8 developed cholangitis, 21 developed pancreatitis, and 10 patients had delayed bleeding, and no patient died. Among these 272 successful removal cases, successful bile duct stone removal was achieved after the first lithotripsy in 211 patients, whereas 61 patients underwent multiple sessions of lithotripsy. As for the 61 patients that underwent multiple sessions of mechanical lithotripsy, 6 (9.8%) had post-procedure cholangitis, 12 (19.6%) had pancreatitis, and 9 patients (14.7%) had delayed bleeding. Compared with the 211 patients undergoing a single session of mechanical lithotripsy, 3 (1.4%) had cholangitis, 1 (0.4%) had delayed bleeding, and 7 patients (3.3%) had pancreatitis. Statistical deviation was present in post-procedure cholangitis, delayed bleeding, and pancreatitis of both groups.

CONCLUSION: Mechanical bile stone lithotripsy on difficult bile duct stones could produce around 90% successful rate. Moreover, complications are minimal. This finding further confirms the significance of mechanical lithotripsy in the treatment of patients with difficult bile duct stones.

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Key words: Common bile duct stones; Mechanical lithotripsy

INTRODUCTION

Since the introduction of endoscopic papillotomy (EPT) in 1974 by Kawai et al.[3], endoscopic management of common bile duct stones has become the approach of choice. At present, the mainstream stone removal procedure is to combine EPT with the Dormia basket or balloon catheter. Several series have shown that 90% of common bile duct stones can be effectively treated by this method.[2,3] Bile duct stones that could not be removed directly through Dormia basket or balloon catheter are called the difficult bile duct stones. These stones may be crushed through simple mechanical lithotripsy and the success rate may be increased by 4% to 8%[4,5], with the usual success rate reported ranging from 51% to 100%[6-10]. In addition to the mechanical lithotripsy, the following procedures may also be used for the treatment of difficult bile duct stones: electrohydraulic lithotripsy (EHL)[11,12], extracorporeal shock wave lithotripsy(ESWL)[13,14], and Laser therapy[15,16]. However, these procedures require the use of specialized and costly equipments. This paper studied the mechanical lithotripsy procedure that used simple equipments, as well as reports on the success rate and outcome of such a procedure on patients.

MATERIALS AND METHODS

From August 1996 to December 2002, Mackay Memorial Hospital recorded a total of 3 632 patients undergoing endoscopic retrograde cholangiopancreatography (ERCP). Among the 1 256 patients who were found to have bile duct stones, 38 patients were directly referred to the surgeons (8 patients had distal CBD stricture, 10 patients had a history of a subtotal gastrectomy, Billroth type II, 3 patients had papilla in big diverticulum, 17 patients had oversized stones). Among the remaining 1 218 patients who underwent sphincterotomy stones were removed in 914 patients using the Dormia basket or balloon catheter, and stones could not be removed in 304 patients by the Dormia basket or balloon catheter that were the so-called difficult bile duct stones. These 304 patients were included in this study. There were 128 males and 176 females; the mean of age was 70.5 years (ranging from 35 to 90 years). Ninety-one patients had a single bile duct stone, whereas 213 patients had multiple stones. The sizes of stones ranged from...
11 to 38 mm, averaging 17.6 mm. The Olympus side viewing scope (Standard JF-240, Olympus Optical Co., Tokyo, Japan) was used for the ERCP examination. The Zimmern type papillotomes (PTH-30, Wilson Cook, Winston-Salem, NC, USA) were used for the sphincterotomy. After the sphincterotomy, the Olympus BML-4Q lithotripter (Olympus Optical Co., Tokyo, Japan) was used on patients whose stones could not be removed by the Dormia basket or balloon catheter. Through-the-scope lithotriptors consist of a large hard-wire basket with an additional metal spiral sheath. If mechanical lithotripsy was anticipated, the lithotripter basket was introduced into the common bile duct with the x-ray photo monitoring to reach the position of the stone. The metal sheath was then advanced over the basket into the CBD. When in position, a metal basket was opened to capture the stones. Thereafter, the basket was pulled back to the external hard-duct of the lithotripter and lithotripsy was performed using the cranking mechanism provided and stones were grasped securely. Under the x-ray monitor, one could see the stone being shattered into many fragments to flow out of the incised papilla. All parts including the basket were constructed for re-use. Thereafter the Dormia basket or balloon catheter might be used to clean out the remaining stones. Most of the patients were treated in one lithotripsy session under conscious sedation, while some patients with multiple and large stones who could not tolerate long periods of lithotripsy were treated in multiple sessions scheduled three days apart. We grouped all single session lithotripsy patients under group A, and all multiple sessions lithotripsy patients under group B. Separate post-lithotripsy records were made for each group that included age and gender of each patient, presence of juxtapapillary diverticulum, size and quantity of the stones, and the number of lithotripsy procedures required. Possible complications included cholangitis, pancreatitis, delayed bleeding and duodenal perforation.

Statistical analysis

Variables among the treatment groups were compared, assuming a 95% probability for rejection of the null hypotheses. A parametric statistic (student’s t-test) was used to compare continuous variables (age and stone size), and a non-parametric statistic (chi-square test or Fisher’s extract test) was used to compare categorical data (juxtapapillary diverticulum, cholangitis, delay bleeding and pancreatitis). A $P$ value <0.05 was defined as statistically significant.

RESULTS

Of the 1 256 patients with common bile duct stones, 304 had difficult bile duct stones. Complete removal of difficult bile duct stones was achieved in 272 patients (89.5%). Unfortunately, mechanical lithotripsy was not able to successfully remove the stones in 32 patients. Of these, 27 cases failed because the stones were too large or because the stones had filled the entire bile duct, so that the mechanical lithotriptor could not be opened to capture the stones. Five of the failed cases were due to distal CBD strictures. Of these 32 failed cases, 29 later underwent surgery. Twenty-seven patients recovered eventufully but 2 patients developed cholangitis and fatal septicaemia. Because of advanced age or poor surgical risk, the other 3 patients underwent plastic stent drainage. Unfortunately, all these patients died within a year.

For the entire group of 304 patients with difficult bile duct stones, stone size averaged 17.6 mm. Stone size averaged 17.1 mm in the 272 successfully treated patients and was significantly larger at 21.9 mm in the 32 failed cases ($P<0.05$). In the group of 272 successfully treated patients, procedure-related morbidity was noted in 30 patients (11%). Nine patients had post-procedure cholangitis (3.3%) and recovered with the use of antibiotics. Nineteen patients had clinical pancreatitis symptoms (hyperamylasemia with upper abdominal pain) (7.0%) and recovered with supportive therapy. Ten patients had delayed bleeding (3.9%). Juxtapapillary diverticulum was noted in 109 of 272 cases (40%). No patient developed duodenal perforation or died because of the lithotripsy procedure. Among the 32 failed cases procedure-related morbidity was noted in 7 patients (21.9%). Four patients had post-procedure cholangitis (12.5%) and recovered after receiving antibiotic treatment. Clinical pancreatitis was noted in 5 patients (15.6%), all of them recovered with supportive therapy. Delayed bleeding was noted in 2 patients (6.2%). Juxtapapillary diverticulum was noted in 14 of 32 cases (43.7%). No patient developed perforation or died because of the lithotripsy procedure (Table 1).

Among the 272 patients whose bile duct stones were removed, 211 patients were treated in one session while 61 patients required multiple sessions of lithotripsy (58 patients had two, and 3 patients had three). Of the 211 patients who had a single session of mechanical lithotripsy (group A), stone size averaged 16.7 mm, 3 patients (1.4%) had post-procedure cholangitis, 7 (3.3%) had clinical pancreatitis and 1 (0.4%) had delayed bleeding.

Juxtapapillary diverticulum was present in 27 cases (44.2%). No perforation was noted in all cases. As for the 61 patients who underwent two or three sessions of mechanical lithotripsy (GroupB), stone size averaged 18.3 mm, 6 of them (9.8%) had post-procedure cholangitis, 12 (19.6%) had clinical pancreatitis, and 9 (14.7%) had delayed bleeding. Juxtapapillary diverticulum was present in 27 cases (44.2%). No perforation was noted in all cases. Statistically significant difference was present between the two groups in regards to the stone size, post-procedure cholangitis, clinical pancreatitis, and especially delayed bleeding ($-0.4 \% \pm 14.7 \%, P<0.001$) (Table 2).

Therefore, if patient tolerance allowed it, a single session to completely remove the stones was recommended to lessen the risk of development of complications.

In the entire group of 3 632 ERCP cases, 588 patients had juxtapapillary diverticulum (16.2%). Among the 1 218 patients with bile duct stones, 546 patients had juxtapapillary diverticulum (43.5%). However, among the 2 414 patients who did not have bile duct stones, 546 patients had juxtapapillary diverticulum (16.2%). Among the 1 218 patients with juxtapapillary diverticulum, 272 patients (40%) had bile duct stones, 546 patients had juxtapapillary diverticulum (43.5%).

Table 1 Characteristics of success and failure of patient groups

| Characteristic          | Success (n = 272) | Failure (n = 32) | $P$ value |
|-------------------------|-------------------|-----------------|-----------|
| Mean age                | 69.7              | 71.2            | 0.236     |
| Sex (F/M)               | 156/116           | 20/12           |           |
| Mean of stone size      | 17.1 mm           | 21.9 mm         | <0.0001   |
| Juxtapapillary diverticulum | 109 (40.1%)   | 14 (43.7%)      | 0.689     |
| Cholangitis             | 9 (3.3%)          | 4 (12.5%)       | 0.037     |
| Pancreatitis            | 19 (7.0%)         | 5 (15.6%)       | 0.154     |
| Delay bleeding          | 10 (3.7%)         | 2 (6.2%)        | 0.366     |
| Perforation             | 0                 | 0               |           |

Table 2 Characteristics of single and multiple session mechanical lithotripsy groups

| Characteristic                | Group A (n = 211) | Group B (n = 61) | $P$ value |
|-------------------------------|-------------------|-----------------|-----------|
| Mean age                      | 69.3              | 70.8            | 0.202     |
| Sex (F/M)                     | 122/89            | 34/27           |           |
| Juxtapapillary diverticulum   | 82 (38.9%)        | 27 (44.2%)      | 0.448     |
| Mean of stone size            | 16.7 mm           | 18.3 mm         | <0.0001   |
| Cholangitis                   | 3 (1.4%)          | 6 (9.8%)        | 0.0012    |
| Pancreatitis                  | 7 (3.3%)          | 12 (19.6%)      | <0.0001   |
| Delay bleeding                | 1 (0.4%)          | 9 (14.7%)       | <0.0001   |
| Perforation                   | 0                 | 0               |           |

Group A: single session of mechanical lithotripsy; Group B: multiple sessions of mechanical lithotripsy.
DISCUSSION

Since Denling et al [7] first introduced mechanical lithotripsy in 1982, the success rate of difficult bile duct stone removal has greatly increased. The original series included 162 patients undergoing mechanical lithotripsy, and success rate was reported to be 84% and complication rate was merely 1.8%. These statistics built up the general confidence on the efficacy and safety of mechanical lithotripsy.

It was reported that an oversized stone was a major factor accounting for failure of mechanical lithotripsy [10,18]. Since stones exceeding 3 cm in size could not be wholly captured by the mechanical lithotripsy basket. However, some extra large stones could still be partially captured. We had 5 patients who had stones larger than 3.5 cm (the largest was 3.8 cm) which were successfully removed from 3 patients. Based on our experience, the mechanical lithotripsy basket can still capture parts of the huge stones and break them into smaller stones. Thereafter, the smaller stones are entirely captured and shattered. What perplexed us was that in some patients the stones not only grew in size, but also multiplied, clogging the entire bile duct, such that the mechanical lithotripsy basket could not be opened to capture the stones. We believe that this is the primary factor causing the failure of the mechanical lithotripsy. Another factor is the presence of distal CBD stricture, which made it impossible to remove even shattered stones as small as 0.5 cm in size.

Some patients could not endure the prolonged lithotripsy treatment period, and the procedure had to be conducted in several sessions (for this paper, the maximum number of sessions was three). Hence, general anesthesia has been recommended by some authors [19]. This is indicated when stones are exceedingly large, since breaking the procedure into two sessions could easily cause patients with obstructive jaundice to develop cholangitis. Moreover, tendency for delayed bleeding would also be greater. Patients with obstructive jaundice had a greater bleeding tendency and the passage of stones through the orifice of the papilla, now enlarged after an EPT procedure, could easily result in bleeding and increase risk of complications. We found in our patients, if the procedure was to be conducted in two sessions, chances of delayed bleeding increased.

Numerous studies have shown that residual stones that are not excreted could easily become the nidus of the recurrent stone [20-23]. Therefore, stones should be removed as completely as possible. We suggest that saline irrigation is helpful and should be repeated several times until all the bile drainage are totally clean, thereby decreasing risk of the development of recurrent stones.

During the past 2 decades, there has been continuous evolution of techniques and instrumentation of endoscopic sphincterotomy (EPT). Early complications of EPT, including cholangitis, acute pancreatitis, bleeding, duodenal perforation, and basket entrapment, occurred in 5.9% to 19.8% in other studies [23-27]. In our study early complications were observed in 37 of 304 cases (12.2%). This value is high compared with that in recent studies. The complication rate was 11% (30 of 272 cases) in even successfully treated group was high, but it was just 3.8% (8 of 211 cases) in the single session of successful group. This difference is statistically significant (P < 0.001).

Several authors reported that a stent should be placed for bile drainage if the CBD stones could not be removed in the first session of mechanical lithotripsy [27-29]. Biliary stent placement has been established as a convenient and minimally invasive treatment for difficult stones, but we did not do it in our series. This probably accounted for the increased early complication rate (11%) in the totally successful group. We have since revised our protocol to stent the common bile duct for bile drainage if the CBD stone removal is incomplete, before we do the next session of mechanical lithotripsy.

The hardness of the stones did not seem to be a factor of failure. The stones of most Oriental people are often pigment stones, and have a harder consistency than cholesterol stones in Westerners. However, we did not encounter any stones that were not shattered due to their hardness. On the other hand, the correlation between juxtapapillary diverticulum and CBD stones has been reported in numerous studies [30-32]. Juxtapapillary diverticulum may contribute to cholangitis and could cause abnormal bile flow and contribute to recurrent biliary stone formation. Hagege et al [33] found that juxtapapillary diverticulum was associated only with bile duct stones and not with gallbladder stones. Of our 1,258 patients with CBD stone, 546 had juxtapapillary diverticulum (43.4%). In the 2,367 cases that did not have CBD stones, only 92 patients had juxtapapillary diverticulum (3.9%). This statistical difference is very apparent.

Electrohydraulic lithotripsy (EHL), using a baby-mother scope system, may also be used for difficult CBD stones in addition to mechanical lithotripsy. The motherscope has a 5.5 mm operating channel to accommodate the babyscope. The babyscope is 4.1 mm in external diameter and has a 1.7 mm operating channel. EHL works on the principle that sparks discharged under water generate high-frequency hydraulic pressure waves. Because these shock waves can also destroy normal tissues, it is important that the probe is placed close to the stone and away from the bile duct wall. The shock wave impulses are fired at the stone’s surface under cholangioscopic guidance until adequate stone fragmentation is achieved. Thereafter, under the continuous feeding of normal saline, electric shock is directly administered to the stone to shatter it. However, this procedure needs the excellent coordination of two very experienced endoscopists, as well as the use of costly and fragile endoscopes. Removal rate of the bile duct stones has been reported to range from 74% to 98% [31,32].

Although laser-induced shock wave lithotripsy has been used in shattering huge stones, the equipment is very expensive and the procedure could easily lead to bile duct injury. Newly developed laser with an automatic stone recognition system has become available [34]. It is a flash lamp-pumped, pulsed laser with a tissue-stone recognition system that can identify bile duct stones by analyzing backscattered light and interrupt the pulse in case of tissue contact. One series reported a bile duct stone removal rate as high as 97% [34], but the treatment has not gained wide usage.

Difficult bile duct stones could also be fragmented by external shock wave using extracorporeal shock wave lithotripsy (ESWL). The second and third generations of ESWL machines do not need a waterbath or general anesthesia and therefore increase patient comfort. Unfortunately, many studies reported that the removal rate of bile duct stones under this procedure was only 80% (range 53-91% for stone fragmentation and 58-86% for complete ductal clearance), not a very ideal rate [35-37]. Schreiber et al [38] reported a complication rate of 35%, wherein 31% was mild and 4% was severe. Besides, patients needed to undergo serial endoscopy examinations and repeat treatments. Therefore, it has not been considered the first line treatment of difficult bile duct stones.

Using the endoscope to treat CBD stones is a very specialized field. It has been reported that in endoscopy centers where cases exceeded 1,000 cases, the application of mechanical lithotripsy yielded high success rates and low complication rates [39]. If an experienced endoscopist was available to administer the treatment, this simple and inexpensive mechanical lithotripsy procedure could resolve many bile duct stone or even many difficult bile duct stone problems. Treatment efficacy of 90% could be achieved without the use of special costly equipments such as EHL, ESWL, and laser therapy. Moreover, complications were minimal especially in single session treatments. Our results further support the significant value of
the simple mechanical lithotripsy in the treatment of difficult bile duct stones.

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