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ORIGINAL ARTICLE

Endoscopic Management and Role of Interim Plastic Biliary Stenting in Large and Multiple Pigmented Common Bile Duct Stone

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ABSTRACT

Background/Aim: Different endoscopic modalities are available for the extraction of common bile duct (CBD) stones. However, there is no clear consensus on the better therapeutic approach. Aim of the study was to analyze the effectiveness of endoscopic retrograde cholangiopancreatogram (ERCP) and endoscopic sphincterotomy (ES) and the role of 'interim' plastic biliary stent deployment in difficult pigmented CBD stones.

Materials and methods: One hundred and sixty-three patients with CBD stone who underwent ERCP and ES between May 2006 and August 2010 were included in the study. Patients with incomplete clearance of stone underwent an 'interim' 10 cm 7 Fr size plastic stent. Approximately 3 weeks later, stone removal was attempted.

Results: ERCP and ES with stone clearance were successful in 114 (69.9%) patients. The mean size of the stone was 1.5 cm ($p < 0.0001$). In 21.5% patients in whom ERCP and ES was not successful, stone retrieval was possible after plastic stent deployment after a median of 24 days. The median number and size of stones per patient was significantly reduced after biliary stenting compared with before [5 (3) *vs* 2 (1) ($p < 0.0001$)], [2.8 (1.5) *vs* 2 (1) ($p < 0.001$)], respectively.

Conclusion: Plastic biliary stenting for difficult common bile stones becoming decrease in stone sizes. Unlike cholesterol stones, stent placement of 3 weeks was related with large and/or multiple stones becoming decrease in size and/or disappearing without unplanned events in pigment stones.

Keywords: Endoscopic retrograde cholangiopancreatography, Endoscopic sphincterotomy, Choledocholithiasis, Common bile duct stones.

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INTRODUCTION

Patients with symptomatic gallstone and common bile duct (CBD) stones predispose an individual to several complications. Today, endoscopic sphincterotomy (ES) with endoscopic removal of CBD stones is an accepted modality of clearing CBD stones and is an alternative to surgery. It is an effective and safe procedure and can relieve symptoms such as cholangitis and pruritus.[1] The procedure ensures complete clearance of the CBD stones. In 20 to 30% of cases, however, duct clearance is incomplete.[2,3] This occurs with large stones. Endoscopic retrograde cholangiopancreatogram (ERCP) and CBD exploration for stones are safe in elderly patients as well and in high risk, surgical candidates. It is an acceptable alternative to operative exploration of CBD for stones during cholecystectomy.[4] Occasionally, the procedure may fail due to anatomical abnormalities such as the presence of a periampullary diverticula, bile duct stricture or previous surgery (Billroth II gastrectomy). The aim of the present study was to analyze the effectiveness of ERCP and ES in clearing CBD stones and the role of plastic biliary stent deployment in difficult CBD stones.

MATERIALS AND METHODS

A prospective study was undertaken between May 2006 and August 2010 consecutive patients with CBD stones who underwent ERCP, and ES were included for the study. Apart from this other inclusion, criteria included high-risk patients with cholangitis elderly patients, high-risk candidates for surgery, comorbid illness such as cerebrovascular disorder, cardiopulmonary diseases, individuals on anticoagulant and/or antiplatelet drugs. Exclusion criteria were patients with biliary stricture. Following ES, the color of bile (green/yellow/purulent) and stone was noted and bile was sent for culture. Antibiotics (cefotaxime 1 gm) were given before and after the procedure. Post procedure, patients were monitored for complications like bleeding, perforation or pancreatitis. Dormia basket or balloon catheter was used to clear the stones within the CBD. Balloon sweeping was done to confirm complete extraction of the stones. Plastic stent 10 cm 7 Fr was deployed in patients in whom the retrieval was impossible because of the size of the stone or due to impaction. The diameters of the CBD stones were measured on the radiographs before and after stenting. CBD stone size was corrected for radiograph magnification by multiplying the ratio of the actual and measured diameters of the duodenoscope on cholangiography and is presented as the maximum transverse diameter by the maximum longitudinal diameter. Change in stone size or fragmentation were assessed at the time of ERCP and stone extraction attempted. Patients with multiple CBD stones, the numbers of the stones were counted and also were measured. Approximately, 3 weeks after stent placement, sphincterotomy followed by attempted stone extraction was done by using a basket/

balloon basket/balloon catheter. No oral dissolution agent or associated medications for bile duct stone were prescribed to any patient.

STATISTICAL ANALYSIS

Data was collected using a standardized proforma. Quantitative data are summarized by the mean or median values, as appropriate. To compare the differences in variables between the initial and second ERCP, the Wilcoxon signed-rank test was used. $p < 0.05$ was considered as significant. SPSS 16.0 version statistical software was used for statistical analysis.

RESULTS

One hundred and sixty-three patients underwent ERCP and ES. There were 74 men and 89 women. A total of 118 (71.2%) patients had been coexisting with gallstones. The mean age was 48.7 years (range: 13-87 years). Indications for ERCP included obstructive jaundice in 89 (54.6%) with cholangitis in 47 (28.3%), intense pruritis secondary to bile duct stricture in 19 (11.6%), for retained stones within the CBD in five (3.1%), and pregnancy associated CBD stone in three (1.8%) patients. ERCP and ES with stone clearance were successful in 128 (78.5%) patients. The mean size of the stone was 1.5 cm (0.3-1.8 cm) ($p < 0.0001$).

The bile was purulent in 21, yellow and thick in 25 and greenish yellow in the remaining. The color of the CBD stones was black and amorphous in 80%, brown and muddy in 15% and in 5% the stones were yellowish brown in color. Of the 14 (8.6%) patients, in whom the stones could not be cleared due to the size and numbers, in five patients the size of the stone varied from 2.5 to 3.5 cm and in 9, the size was more than 5 cm. Bile culture was positive in 18%.

In 35 (21.5%) patients in whom ERCP and ES were not successful in the first instance, a plastic stent 7 Fr 10 cm was deployed. Endoscopic placement of biliary plastic stent was successful for all patients without unplanned events. These 11 patients had multiple CBD stones (>3) and 26 patients had large stones (>2 cm). Stone retrieval was possible after a median of 24 days (19-38 days). The mean size of the stone was 2.4 cm (1.9-2.8 cm). After biliary stenting for 3 weeks, all patients had some reductions in the stone number and/or stone size. In six patients, there was spontaneous clearance of the stones from the CBD. The median number of stones per patient was significantly reduced after biliary stenting compared with before [5 (3) *vs* 2.0 (1.0) ($p < 0.0001$)]. The median size of the stone was also significantly decreased from [2.8 (1.5) to 2.0 (1.0) after stenting ($p < 0.001$)] (Table 1). All the stones were black and amorphous in consistency. ERCP-related post procedure complications included mild acute pancreatitis in one and sphincterotomy related bleed in one. Both the patients were managed conservatively. Recovery was uneventful. There was no procedure-related mortality.

Table 1: Comparison of number and size of common bile duct stones before and after 3 weeks of plastic stent placement in 35 patients

Features	*Prestenting*	*Poststenting*	*p-value*
Size of the stones range (mean)	1.9-3.2 (2.4)	0.4-2.1 (1.4)	<0.011
Number of stones range (mean)	1-5 (3)	0-3 (2)	<0.0001

DISCUSSION

More than 80% of all CBD stones can be effectively treated with EST and stone extraction using baskets and balloon or mechanical lithotripsy. Large CBD stones (≥2 cm in diameter) can be difficult to extract by conventional methods like balloon/basket. Mechanical lithotripsy was used for stone extraction. However, the technique may fail in very large stones, multiple stones, or stones within a relatively narrow duct where there is little space to manipulate the basket. Various factors, such as presence of the periampullary diverticulum, narrowing of the distal CBD, multiple CBD stones, limited sphincterotomy due to a small papilla, more acute distal CBD angulation, and a shorter length of the distal CBD arm, all may influence successful stone clearance.[5,6] In the present study, we observed that stone size of less than 1.5 cm (0.3-1.8 cm) could be successfully cleared by ERCP and ES. Further, 21.5% of stones 2.4 cm (1.9-2.8 cm) in size could be retrieved subsequently after a median period of 24 days following an interim plastic stent deployment after failed ERCP with ES. Silvis et al observed that stones greater than 20 mm were beyond the size of a safe sphincterotomy.[7] While others have suggested that stenting is mandatory for stones larger than 15 mm.[8,9]

As expected, the possible factors that determine the chances of fragmentation or reduction in stone size are the composition of the stones. It was reported that brown pigment stones were soft and were characterized as easily dissolved or crushable, in contrast to black pigment stones and cholesterol stones, which are often hard and more difficult to reduce in size, or only disintegrate after a long-term placement of a plastic stent.[10] In the Western world, approximately 30% of gallstone carrier's exhibit black pigment gallbladder stones.[11] Pigment gallstones are the second most common type of gallstone. Although pigment gallstones comprise only 15% of gallstones in individuals from Europe and the Americas, they are more common than cholesterol gallstones in Southeast Asia. Pigment stones predominate in the rural Orient, in cirrhosis, and in elderly United States patients undergoing cholecystectomy.[12] In

Taiwan, Ho et al studied the characteristic of all stones, during the past 15 years the relative frequencies for mixed, formed pigment, and muddy pigment stones had been roughly 40, 40 and 20%, respectively.[13] The color of the CBD stones was black and amorphous in 80%, brown and muddy in 15% and in 5% the stones were yellowish brown in color in our study.

In addition, the procedure time is often prolonged when one must clear many stones. Many patients with difficult CBD stones are of older age or have severe comorbid diseases. For these cases, alternative methods, such as extracorporeal shockwave lithotripsy (ESWL), laser lithotripsy and electrohydraulic lithotripsy (EHL), are often used. Mechanical lithotripsy was introduced for large uncxtractable stones after ES failed to clear the duct. However, to be successful, the stones must, firstly, be securely captured by the basket for crushing. This may fail if stones are too large, firmly impacted or poorly accessible.[14] The use of mechanical lithotriptors in a public hospital is also questioned because of their expense and unwieldy nature.[15] These procedures, however, are time-consuming and require delicate instruments that are often not available in general institutions. Laser's lithotripsy, an alternative mode of treatment, requires advanced training of endoscopists and more sophisticated and expensive equipment. The widespread use of these systems is therefore limited.[16] An easier and efficient method is needed, especially in the developing countries where expensive equipment and high technology are not available and in the treatment of old and frail patients who cannot tolerate prolonged and complicated procedures. It has been reported that peroral endoscopic EHL is an effective means of managing difficult biliary stone disease, with fragmentation rates of 96% and stone clearance rates of 90%,[17] whereas laser lithotripsy has a success rate of 67 to 88%.[18-21] However, these techniques are limited to tertiary institutions or referral centers and are associated with a complication rate of 10% and a mortality rate of 1%.[23] In addition, there are still a significant percentage of difficult stones that cannot be removed even after mechanical lithotripsy, EHL or ESWL.[23,24]

Plastic stent placement for 3 weeks was generally associated with a reduction in both the number and the size of CBD stones. The continuous friction between the plastic stent and the stones can produce stress forces that facilitate the disintegration of stones and reduce the stones' size. With the continuous friction, the stones disintegrate and can subsequently be extracted with the basket, balloon, lithotripsy or a combination. This is of special benefit to fragile and elderly patients. However, the mechanism of stones changing with the number and size is unclear. Some possibilities include friction between the plastic stent and stones, the influx of duodenal contents, or both. Because the plastic stent is thought to easily move with the intestinal movements, the friction between the stent and stones is expected to be much larger than that of friction between stones *in situ*. An endoscopic biliary stent is still essential to achieve good bile flow so as to decrease the frequency of stent exchange and prevent stone impaction and cholangitis. Short-term use of a biliary stent, followed by further endoscopy or surgery, is recommended to ensure adequate biliary drainage in patients with CBD stones that have not been extracted.

Several studies have reported therapeutic indwelling stenting for bile duct stones.[25-28] These studies reported a decrease in stone size and/or stone fragmentation, apart from relieving cholangitis and pruritis. In 35 patients in the present series, CBD stone could be retrieved/clear from the CBD after a median period of 24 days (19-38 days). There was difficulty in extraction during initial ES. In six patients, there was spontaneous clearance of the stones from the CBD. An earlier study had shown successful retrieval of CBD stones after a median period of 63 days following a stent *in situ*, as a treatment protocol for difficult CBD stones. The stone size decreased from 24.9 to 20.1 mm.[25]

Jain et al,[26] reported that 35% patients complete clearance of CBD stones following a second ERCP after 6 months. In 20% of patients the stones had become smaller, were fragmented and could be easily extracted. One-third of patients in this series, however, continued to have large stones.

Katsinelos et al,[27] in their series found that 44% of stones were either reduced in size or had fragmented after biliary stenting. Horiuchi et al[28] have reported that stone clearance was possible in 93% (37/40) in a series of 40 patients with large (>20 mm) and/or multiple (>3) large stones. The median size index reduced from 4.6 to 2.0 over a median period of 65 days. The success of retrieving CBD stones after stent placement may be related to the friction excited between the plastic stent and stones[9] and influx of duodenal contents[26] or both.[27]

In our series, the CBD stones were completely cleared after ES in 69.9% patients with further clearance after stent deployment in 21.5%. Laparotomy or laparoscopic duct exploration is an alternative for clearing large CBD stones[29] and this was necessary in 14 patients in our study. Endoscopic stenting is a safe and effective therapy in the management of difficult bile duct stones and stones that remain unextractable by other endoscopic methods. Both morbidity and mortality are reported to be low. Biliary drainage can be achieved temporarily, thus allowing definitive surgery

to be postponed in those otherwise high-risk patients. The present study also has limitations because the analyses were a relatively small number of patients, and it lacked a control group.

CONCLUSION

We conclude that these data suggest that for patients with difficult stones that are speculated to be difficult to extract, the elderly or high-risk patients, medically unfit for surgery, endoscopic stenting is the definitive mode of an effective alternative for the management of difficult CBD stones with a good outcome. In places where advanced and costly lithotripsy methods arc not available, this combined method is the most effective alternative. ES with interim plastic stent *in situ* within the CBD for a period of 3 weeks can further assist in extraction of CBD stones up to 2.5 cm in size. Unlike the reports from the West wherein a median period of 63 to 65 days have been recommended for interim stent placement for future stone retrieval[25,27] shorter period of deployment is sufficient for our patients as majority of the stones are either black or mixed and are amorphous,[30] unlike the hard cholesterol stones reported from the West. The present study further highlights that unlike cholesterol stones, a short period stenting to make subsequent removal easier for large and/or multiple CBD stones.

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