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Full Length Research Paper

Treatment of Large and Difficult Common Bile duct Stones using Endoscopic Plastic Stenting

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Plastic stents inserted during ERCP is a common procedure for establishing biliary drainage in patients with large stones. As there is no definite evidence for the effect of plastic stents on stone size, this study was conducted to throw a light on this issue comparing stone size before and months after stent insertion. Plastic biliary stenting was performed during endoscopic retrograde cholangiopancreatography (ERCP) for 20 patients who had huge common bile duct stones or those difficult to remove with balloon or dormia basket. The diameter of stones was ≥15 mm in all patients. Sphincterotomy, and endoscopic placement of 10 Fr plastic biliary stents were established in all patients. Comparison of stone size before and 6 months after stent insertion were documented. The complete stone clearance rate after treatment was obtained. After plastic stent insertion for 3–6 months, the biliary stones were absent or became sludge in 4 (4/20) patients, and reduction in stone sizes became evident in 15 patients, in whom the stone median size was significantly decreased from 23.1 mm to 15.4 mm. The biliary passages were cleared from stones in 18 (18/20) patients, either due to their change to sludge (4 patients), or the stones were extracted successfully with basket, balloon or a combination (in 14 patients). The remaining two patients (2/20) demonstrated no significant changes in stone sizes. Plastic biliary stenting may destroy common bile duct stones and reduce their sizes. This is an effective and applicable alternative to clear large or difficult common bile duct stones.

Keywords: Large Stones, Endoscopic Retrograde Cholangiopancreatography, Plastic Stent.

INTRODUCTION

More than 20 million people in the United States of America are affected by gallstone disease with an annual cost of 6.5 billion dollars (Anderson et al., 2011). Moreover, cholelithiasis and complications related to it necessitate surgical intervention in a large number of patients with about 700,000 cholecystectomies performed yearly (McHenry and Lehman, 2006). Nearly 10–15 % of patients undergoing cholecystectomy are discovered to harbour common bile duct stones (choledocholithiasis) (McHenry and Lehman, 2006). This means that 70,000–100,000 patients will need more intervention for biliary stones every year, of which many may need more than one treatment (McHenry and Lehman, 2006). Biliary stones can range from 1 mm to greater than 30 mm in diameter; surprisingly stones up to 7 cm in size have been described in patients with a hugely dilated CBD (Trikudanathan et al., 2014). Endoscopic sphincterotomy (EST) and subsequent stone extraction is a widely accepted treatment option for common bile duct (CBD) stones and this approach can make the bile ducts clear of stones in 85% to 90% of patients (Chopra et al., 1996). The number of stones successfully extracted declines with increasing stone

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size (Yasuda and Itoi 2013). Repeated attempts to remove biliary stones with a diameter exceeding 20 mm usually increase the risk of stone impaction and thus fragmentation prior to removal is very important (Trikudanathan et al., 2013). Stones less than 10 mm in diameter are usually extracted intact using biliary balloon and/or retrieval basket, following endoscopic biliary sphincterotomy (Yasuda and Itoi, 2013). This intervention is especially recommended in elderly patients, because surgical exploration of bile duct carries a high morbidity and mortality. We encounter many situation in which it is impossible to retrieve biliary stones, especially large or impacted stones, or in case of an associated narrowing of the distal end of common bile duct. Endoscopic insertion of biliary plastic stent has been used instead of spending long time doing aggressive endoscopic extraction or exposing the patient to surgical exploration especially for frail, elderly patients or in those with high surgical risks. Friction resulting from contact between the stones and the stents introduced alongside them could incite stone fragmentation or decrease the stone sizes, but this is not well established (McHenry and Lehman, 2006). Hence, this study aim to treat large and difficult common bile duct stones using endoscopic plastic stenting.

MATERIALS AND METHODS

This study was conducted between July 2016 and May 2017 on 20 patients who had large CBD stones. They were diagnosed using abdominal ultrasound and/or magnetic resonance cholangiopancreatography (MRCP). All patients were exposed to full history taking and examination. Liver enzyme, bilirubin (total and direct) and coagulation profile were done. The study included only large stones, namely those with a diameter larger than 15 mm, and were not extracted with the conventional endoscopic therapy. Antibiotics were used before and after the procedures (ceftriaxone 1 gm). All procedures were done under general anaesthesia and patients were positioned prone and sedated with propofol. Endoscopic retrograde cholangiopancreatography (ERCP) was performed using an Olympus 4.2 mm channel therapeutic duodenoscope (Tokyo, Japan). EST was done in every patient with basket, and balloon extraction of CBD stones attempted, but failed. In all 20 patients, plastic stents (10 f) were inserted for temporary biliary drainage before further endoscopic attempts to clear duct. All plastic stents were 10 french and the average length was 10 cm and were placed with the proximal end reaching above the stones and the distal stent end in the duodenum. Their extension were confirmed by radiographs and patency and good bile flow were ascertained. The patients were scheduled for stent exchange every 3 months and follow up was done once a month by phone call or with a clinic visit and liver function test. Endoscopic stent were changed at a scheduled 3 month follow up. Therapeutic intervention and exchange of the occluded plastic stent were carried out when recurrent cholangitis and/or elevation of liver enzymes or bilirubin occurred before the scheduled stent exchange. A ruler was used to measure the stone size accurately under the X-ray. Any changes in stone size or fragmentations were evaluated at the time of ERCP, or during the replacement of an occluded non-functioning stent, with stone extraction tried if it seems possible. No medications for bile duct stone were prescribed to any patient.

RESULTS

The patients included 8 men and 12 women with a median age of 67.3 years (range, 55–86 years) (table 1, 2 and figure 1). The patients were considered unfit for surgical interventions because of advanced age or serious concomitant medical disability or both. In 7 of the 20 patients, the gallbladder was absent in situ and 13 cases had stones in the gallbladder. Double plastic stents were used in 4 (20%) cases, single plastic stent were used in 16 (80%) cases. The number of stones was one in 13 patients, (13 out of 20 patients had a single stone in the CBD). Two stones were found in 5 patients, and numerous stones in the remaining 2 patients. The sizes of bile duct stones were $\geq$15 mm in all patients, $<$20 mm in 13 patients, and $\geq$20 mm in the remaining 7 patients (2 cases had stricture of the lower CBD). Successful endoscopic insertion of biliary plastic stent was achieved in all patients. Calcular obstructive manifestations like pain, fever, and jaundice improved dramatically, and the presenting abnormality of liver function and bilirubin were normalized in all patients. 3 months after stenting, contrast injection and cholangiography during ERCP declared that the bile duct stones disappeared or became sludge in 5 patients. This sludge was swept out by using balloon, sweeping out the sludge until the sludge was removed. Fragmentation of the stones or stone size reduction was observed in 15 patients after 3–6 months of plastic stent insertion. The stones were extracted successfully with basket, balloon or combination in 12 patients at the second ERCP and in 6 cases at the third ERCP trial. No change in stone size was observed in the remaining two patients in whom extraction failed and the plastic stents were exchanged and those two patients were referred to surgery. The

Table 1. Characteristics of patients in different-time ERCP, and concomitant diseases

Patient Characteristics	First ERCP (0 months)	Second ERCP (3 months)	Third ERCP (6 months)
Patients, N	20	20	7
Age, Average	55–86	55–86	72–86
Sex Male	8	8	2
Female	12	12	5
Procedures, N	20	20	3
Sphincterotomy	15	0	0
Pre-Cut Sphincterotomy	5	0	0
Complete Stones Clearance, N (%)	0(0)	14(70%)	5(71.%)
Balloon Dilator, N (%)	0 (0)	4 (20%)	4 (57.1)
Basket, Balloon Or Combination	20	14	7
Single Plastic Stenting, N (%)	11 (55%)	4 (20%)	1 (1.2%)
Double Plastic Stenting, N (%)	2 (10%)	2 (10%)	0 (0)
Previous Cholecystectomy, N (%)	7(35%)	7 (35%)	0 (0)
Duodenal Diverticulum, N (%)	5 (20%)	5 (20%)	2 (28.5%)
Clinical Presentation, N (%)	20 (100)	11 (55%)	3 (42.8)
Gallbladder Stone, N (%)	13(65)	13 (65)	7 (100)
CBD Obstruction Or Dilation	20(100)	20(100)	7(100)
Acute Pancreatitis	2	1	0
Concomitant Chronic Disease, N (%)	18 (90)	18 (90)	7 (100)
Diabetes Mellitus	7	7	3
Cardiovascular Disease	10	10	5
Pulmonary Disease	2	2	1
Chronic Renal Insufficiency	1	1	0
Liver Cirrhosis	3	3	2
Complications, N (%)	2 (10%)	2 (10%)	0 (0)

Table 2. Common bile duct stone size changes after biliary plastic stenting in 20 patients

Items	Number (%) Managed by stenting	Initial stones size (mm)	Size of stones after stenting (mm)	Duration of the stenting (months)	Subsequent treatment	Bile duct stones clearance
Complete removal of stones or sludge	4 (20)	15–27 (m 20.1)	0-sludge	2.8–3 (2.9 m)	Balloon retrieval	Yes
Fragmentation of the stones and clearance	15 (75)	16–33 (m 23.1)	11–21 (m 15.4)	3–6 (4.9 m)	Basket, balloon sweeping	Yes
Unchanged stones	2 (10)	25–27 (m 26)	25–27 (m 26)	6 (6 m)	Placement of the plastic stents	No

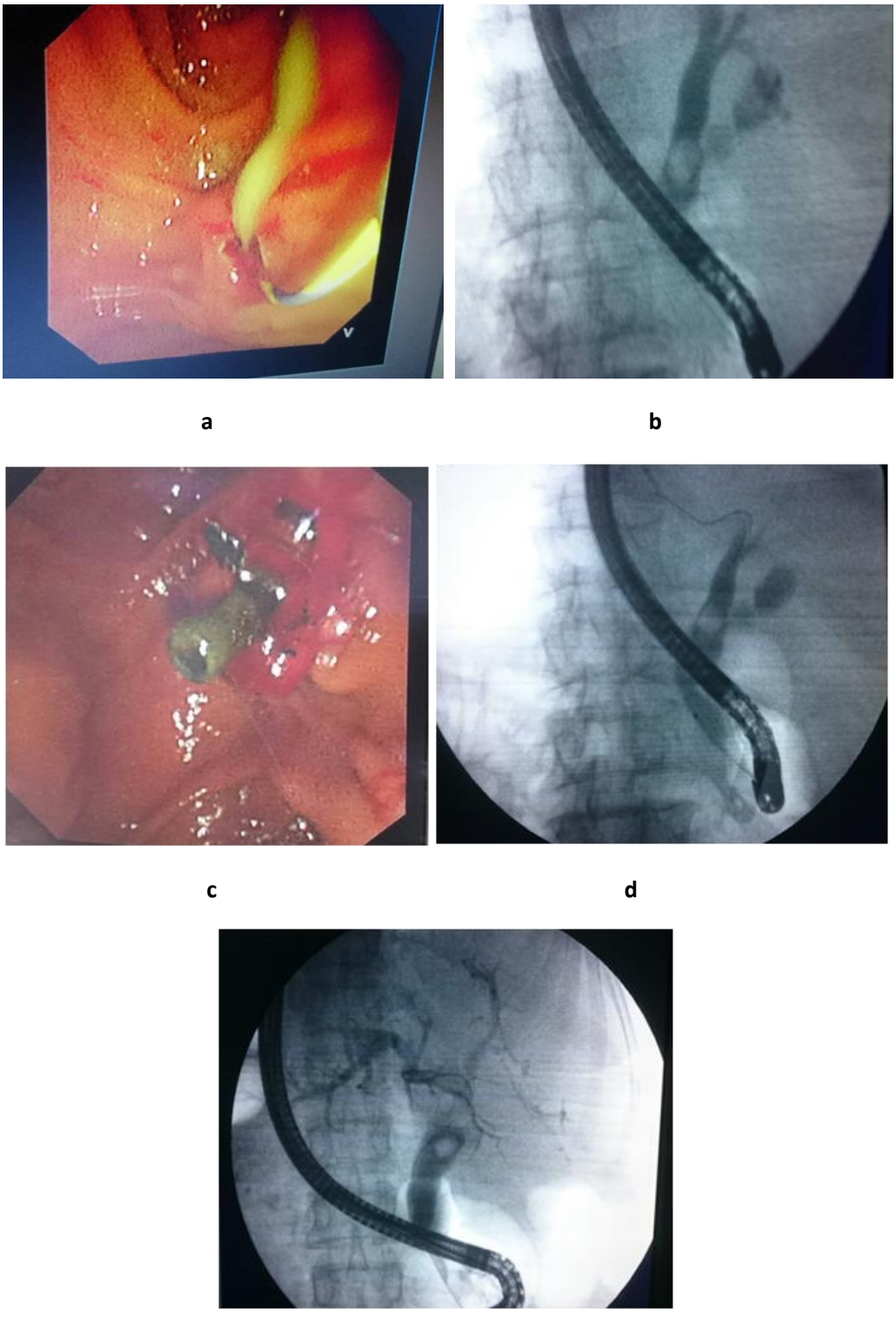

Figure 1. Big CBD stone in a risky patient. A: after sphincterotomy and gush of pus was observed. B: cholangiogram showing big stone. C: Stent after 3 months. D: cholangiogram after 3 months. E cholangiogram after 6 months before stone extraction

complications of ERCP included acute mild pancreatitis (3/20) and mild bleeding (1/20), without perforation or death.

DISCUSSION

About 10–15% of common bile duct stones cannot be removed by conventional extraction techniques (Binmoeller et al.,1993). Difficulties include inability to reach and face the papilla (for example, presence of periampullary diverticulum sigmoid-shaped CBD), big stone diameter (stones with a diameter of >15 mm that cannot be easily retrieved by a traditional balloon or basket), unusually shaped stones (barrel shaped), difficult position of stones (for instance, intrahepatic, in the cystic duct stump, or in a pouch proximal to strictures), multiple biliary stones, Mirizzi syndrome, bad general condition of the patient and bleeding risk (Trikudanathan et al., 2013). Kim et al.2007 conducted a study to assess factors causing technical difficulties during ERCP and suggested that older age (>65 years), previous gastrojejunostomy, big stone size (≥15 mm), impacted stones, short, and severe-acute angulation distal CBD (≤135°) are all contributors to difficulty with endoscopic removal of CBD stones. Following biliary sphincterotomy, mechanical basket lithotripsy has been the first approach for such difficult stones, with a variable success rate of up to 90% (Trikudanathan et al., 2013). With the appearance of it, plastic stent became widely used in situation of difficult stone retrieval to facilitate bile drainage and to decrease possibility of stone impaction, cholangitis or liver function disorder. Therefore, extremely sick or aged patients who posses great surgical mortality risks should be managed with placement of plastic stents, instead of surgery (Hu et al., 2009, Rodríguez-González and Naranjo-Rodríguez, 2003). Explanation of how the stents cause changes in number and size of stones is still obscure. At first, respiratory and intestinal movements make friction between the stents and stones, thus inciting fragmentation and make removal more easy. Also, prevention of stone impaction at the ampulla of Vater facilitates drainage after biliary stenting. In addition, polygonal stones may change to more rounded ones after a period of friction and increases possibility of spontaneous passage (Xiaohua et al., 2016). The ideal type of plastic stent is not known up till now. However, pigtail stents is better than straight endoprosthesis due to lower rates of migration and perforation (Jain et al., 2002; Horiuchi et al., 2010). In one study, straight stents were used in all patients and no stent migration or perforation was observed in any patient. There is no documented time period for plastic stent replacement, although 2 months may be enough to fragment large and/or multiple stones (Horiuchi et al., 2010). Similar results were obtained in this study. The longest safe exchange interval is not established. After insertion, plastic stents should be exchanged after 6 months (Jain et al 2002; Katsinelos et al., 2003). Of the 20 patients in this study, 15 patients having large CBD stones showed decrease in size or fragmentation of stones after 3–6 months of endoscopic plastic stenting. These 15 patients showed significant reduction of stone size from 23.1 mm (16–33 mm) to 15.4 mm (11–21 mm), which permitted the extraction of residual stones with a dormia basket, balloon, and in 4 patients the stones disappeared after stenting treatment or the sludge was swept out using a balloon by ERCP. This study emphasize that there is a great effects of plastic stenting on reduction of stone size and fragmentation of stones after 3–6 months of endoscopic stenting treatment. An important issue is the stenting time in the difficult CBD stones patients. It has not been discussed so far. Cotton et al. reported this technique of plastic stent insertion in 17 elderly and high-risk patients with large bile duct stones, when trials at stone extraction failed. In a follow-up of 2–5 years (median, 39 months), only two required surgery for biliary infection and five have died from other problems. With the advent of ERCP and progress of its accessories, it became now reasonable to manage large stone in frial risky patient by plastic stent insertion (Cotton et al., 1987).

CONCLUSION

Bile duct stones are typically treated with endoscopic sphincterotomy and balloon or basket extraction. In those with large stones, intrahepatic stones, lodged stones, or patients with surgically altered anatomy, stone removal presents many challenges. For those patients withvery large stones, old age, or other serious medical co-morbidities, endoscopic biliary stents can be used as a temporary measure before endoscopic stone extraction or as definitive treatment for patients who are poor candidates for future therapy.

Ethics Committee Approval

The study was approved by the ethics committee of the faculty of medicine Al Azhar university.

Informed Consent

Consent was taken from all patients and the risk of

any complication was explained to them including cholangitis, pancreatitis and bleeding.

Conflict of Interest

No conflict of interest was declared by the authors.

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