Endoscopic Endoprosthesis for Large Stones in the Common Bile Duct

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Endoscopic biliary endoprosthesis was performed for 34 high-risk patients with common bile duct stones too large to be extracted by conventional endoscopic means. Bile duct drainage was established in all the patients without complications. Late complications developed in four patients and included cholangitis (three) and biliary pain (one). Twenty-five patients underwent a second endoscopic retrograde cholangiopancreatography between 4 and 30 months (mean, 15.1) during follow-up. Stone fragmentation was obtained in 76% (19/25) of the patients. Ten patients had complete stone clearance, and nine patients had disintegrated stones which could be readily removed endoscopically. The remaining nine patients were followed up with endoprostheses in situ for four to 60 months (mean, 24.8) without any symptoms. These results suggest that endoscopic endoprosthesis for difficult common bile duct stones is an effective method to clear the duct in selected cases, as well as an important definitive treatment in high-risk patients.

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Introduction

Endoscopic sphincterotomy with stone extraction has become a standard treatment of choice in the management of choledocholithiasis (1). With respect to clearing the bile duct of stones, this technique is successful in 80-95% of cases (2, 3). Large stones that cannot be extracted with the conventional endoscopic means present a greater challenge, and a variety of surgical and non-surgical techniques are now available to remove these stones. However, such techniques are often invasive and at best should be avoided in the management of frail, elderly patients or those with high surgical risk. Endoscopic insertion of biliary endoprostheses has been proposed as an alternative for such high-risk patients (4-10). The major aim of this therapeutic option is directed toward prevention of stone impaction at the ampulla and a subsequent life-threatening complication, cholangitis.

It is preferable, however, whenever possible that all stones be removed after the biliary endoprosthesis, since the presence of a foreign body, the endoprosthesis, is considered to pose a risk for the development of biliary infection (11). As expected, friction produced between the stones and the endoprostheses introduced alongside them might induce stone fragmentation.

But, little is known whether or not the indwelling of the endoprostheses for a considerable period may effect the stone size and thus may provide a chance for subsequent endoscopic bile duct clearance. We report here the results of a follow-up study in 34 patients with large common bile duct stones who were treated with the endoscopic placement of biliary endoprostheses. The effect of indwelling endoprostheses on stone fragmentation was also assessed.

Patients and Methods

During the last 9-year period, 34 patients with common bile duct stones were managed with endoscopic biliary endoprosthesis as a definitive treatment at the initial endoscopic retrograde cholangiopancreatography (ERCP). These 34 patients represented 7.0% (34/486) of the patients who underwent ERCP for stone removal. There were 16 male and 18 female patients; median age was 77.9 year (range, 51 to 88 year). These patients were considered unfit for surgical intervention because of advanced age (more than 80 year, n=17) or concomitant serious medical disability including malignancy (n=6), cardiopulmonary disease (n=8), and cirrhosis (n=3). The indications for ERCP were jaundice (n=10), jaundice and cholangitis.
Diagnosis of cholangitis was made by the findings of fever, pain, and leukocytosis. Suppurative bile was obtained in six patients during endoscopic cannulation of the bile duct. These six patients underwent insertion of a nasobiliary catheter as a temporary means prior to endoprostheses insertion. Twelve patients had undergone cholecystectomy previously for cholecystolithiasis. Nine of the other 22 patients with gallbladder in situ had stones in the gallbladder.

All endoscopic procedures were carried out using a standard technique with a lateral-viewing duodenoscope (JF1T10, JF1T20, or JF200, Olympus Corp., Tokyo, Japan). Prophylactic use of intravenous antibiotics was performed in each patient before ERCP. Informed consent was obtained from all patients. After opacification of the bile ducts with contrast material, the size of the stones was estimated by using the diameter of the scope on the X-ray film as a reference. The number of stones was one in 13 patients, two in 12 patients, and three or more in the remaining nine patients. The largest stone diameter was greater than 20 mm in all patients; less than 30 mm in 17 patients, and 30 mm or more in the remaining 17 patients. Juxtapapillary diverticula were found in 26 patients. In 25 patients, subsequent endoscopic sphincterotomy attempts at stone removal were made using mechanical lithotripsy devices, but they were unsuccessful in all due to the difficulty in trapping the stones within the wire basket. The remaining nine patients were considered unfit for one-stage endoscopic stone removal according to the ERCP findings: giant stones (more than 40 mm) in five patients, multiple stones (more than 8) in three, large duodenal diverticula in one. A double pigtail endoprosthesis (7 Fr in diameter and 7 cm in length) was used. In all cases, the endoprosthesis was inserted so that the proximal pigtail curl could be located above the stones and the distal pigtail curl in the duodenum near the papilla. Thirty-one patients received a single endoprosthesis. The remaining three patients with a markedly dilated common bile duct received two endoprostheses. The second endoprosthesis was inserted to trap stones within a markedly dilated common bile duct and to prevent impaction of the stones at the ampulla.

After these endoscopic procedures, all patients were informed of the possible complications related to long-term endoprosthesis placement, and were requested to contact their physician if symptoms suggestive of cholangitis or jaundice appeared. Patients were followed up every four months mainly by recording clinical symptoms, blood chemistry, and a plain abdominal X-ray. Withdrawal of endoprostheses and endoscopic intervention was performed when symptoms of cholangitis and/or reelevation of alkaline phosphatase or bilirubin levels occurred during the follow-up period.

Twenty-one patients agreed to a second endoscopic attempt to clear the bile duct of stones between 4 and 30 months (13.7 months on average) during their follow-up. Changes in stone size were assessed after the second ERCP.

**Results**

All six patients with symptoms of cholangitis and suppurative bile were successfully treated with temporal nasobiliary drainage (3–7 days) and antibiotics. Endoscopic insertion of biliary endoprostheses was successful for all 34 patients without procedure-related complications. Symptoms such as pain, jaundice, and those of cholangitis disappeared, and the preexisting abnormal elevation of serum alkaline phosphatase levels normalized in all the patients. There were no early (within 30 days) complications.

Late complications occurred in four of 34 patients between 18 and 28 months; cholangitis in three and pain associated with concomitantly elevated serum alkaline phosphatase level in one. Dislodgement of endoprostheses from the bile duct into the duodenum was observed in two patients on plain abdominal X-ray. ERCP demonstrated the impacted stone at the ampulla. Stones in these two patients were substantially disintegrated (less than 10 mm in size) and were all successfully extracted with the use of baskets. In the other two patients, ERCP demonstrated only small fragments of a few millimeters, and the bile ducts were successfully cleared endoscopically.

Table 1 lists the results of the second ERCPs performed in 25

| Table 1. Effect of Biliary Endoprosthesis on Stone Size in 25 Patients |
|--------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| No. of | No. of stones | Initial size | Duration of | Subsequent |
| patients | 1/2/3 or more | of the stones | endoprosthesis | treatment |
| | | (largest diameter in mm) | indwelling (Month) | |
| Complete stone clearance | 10 | 3/5/2 | 20–35 (m 27) | 8–24 (m 13.6) | NP |
| Disintegration of stones | 9 | 4/3/2 | 20–50 (m 32) | 4–28 (m 16.2) | Endoscopic stone extraction |
| Unchanged stone size | 6 | 2/1/3 | 20–40 (m 30) | 4–30 (m 16.2) | Endoscopic replacement of endoprosthesis |

m: mean, NP: not performed.
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Fig. 1. An 82-year-old female patient with choledocholithiasis. A large stone that cannot be captured in the basket of a mechanical lithotripsy device (left). A 7 Fr double pigtail curled endoprosthesis is introduced to establish biliary drainage (middle). Follow-up examination of the patient six months after placement of the biliary endoprosthesis showing complete clearance of the bile duct (right).

Discussion

When endoscopic removal of common bile duct stones fails, insertion of endoprostheses is indicated as a temporary measure to facilitate bile drainage and prevent stone impaction prior to the subsequent surgical intervention. For very ill or elderly patients with unacceptably high surgical mortality, biliary endoprosthesis, instead of surgery, has been considered a definitive treatment. Several reports of small series have been published providing support for the efficacy of this technique (4–10). The present experience reconfirmed the usefulness of biliary endoprosthesis for choledocholithiasis in maintaining sufficient, long-term bile drainage and relieving biliary obstruction. Furthermore, the effect of endoprostheses on the reduction of stone size was confirmed in the present study, indicating that biliary endoprosthesis is not merely a palliative method but may provide a subsequent opportunity to clear the duct with minimal invasion in fragile patients.

Endoscopic stenting using plastic endoprostheses is a well-established technique for palliation of unresectable malignant biliary obstruction by restoring normal bile flow via the endoprostheses across the obstruction. The major drawback of the technique is clogging of the endoprostheses which occurs within several months and necessitates frequent endoprotheses exchanges to prevent cholangitis. As is well recognized, the sphincter of Oddi acts as a mechanical barrier against the reflux of duodenal contents (12). Disruption of this barrier with sphincterotomy or transpapillary insertion of endoprostheses results in bacterial contamination of bile by ascending infection.
Moreover, the presence of a foreign body in the biliary system has been shown to facilitate bacterial adhesion and biofilm formation (11). However, when used for cholecodocholithiasis, blockade of the endoprostheses seems to be an insignificant problem, and the present experience as well as other previous reports have shown that endoprostheses can be left in place for 35–60 months with good results (4–10), a time period far exceeding the expected patency period of endoprostheses. It may be considered that the endoprostheses do not serve as the sole conduit for bile flow when used for choledocholithiasis. As expected, there remains a lumen in the common bile duct after placement of endoprostheses alongside the stones, and this lumen may provide a pathway for bile flow even when the endoprostheses are completely obstructed. In fact, as confirmed in the present 21 patients who underwent a second endoscopic intervention, endoprostheses withdrawn after 4–30 months’ indwelling were inevitably clogged without any signs of biliary obstruction. As long as sufficient bile drainage is maintained, the flushing action of bile may obviate the overt inflammation in the bile duct.

Probably, the major role of biliary endoprosthesis for choledocholithiasis is to trap the stones within the common bile duct and prevent stone impaction at the ampulla. Dislodgement of endoprostheses may expose a patient to the risk of stone impaction and cholangitis. This complication was observed in two patients in the present series. Because stones in these two patients were found significantly disintegrated, reduction in stone size was considered to allow the endoprostheses to fall below the stones and finally pass easily through the sphincterotomized papilla into the duodenum. In the other two patients, signs of bile duct obstruction were found although the endoprostheses were appropriately positioned, and impaction of stone fragments at the ampulla was considered a leading cause in these patients. Because of the presence of endoprostheses, sphincterotomized papilla might not have enough lumen for stone fragments to pass spontaneously. This complication has not been well recognized. Extending the size of the sphincterotomy should be considered when this complication is found and the stones are not disintegrated enough to be extracted by endoscopic means.

No gallbladder symptoms occurred in the 22 patients with gallbladder in situ in the present series during follow-up. The role of endoscopic management of symptomatic bile duct stones in elderly or high-risk patients with gallbladder in situ has been reported if there is no acute gallbladder disease. In a series of 65 patients with gallbladder in situ, only 4 required cholecystectomy for persistent or recurrent symptoms within 6 months after endoscopic sphincterotomy, and the remaining 61 patients were followed-up without symptoms for 12–44 months (14). Although risk factors have not been fully determined for the development of gallbladder complications subsequent to endoscopic sphincterotomy, there seems to be no correlation of the presence, absence, number of gallbladder stones, or the presence of periampullary diverticula with the risk of future problems (15, 16).

The effect of long-term endoprostheses placement on stone size has not been extensively evaluated. As expected, friction between stones and endoprostheses may produce physical force to disintegrate stones. In the present series, disintegration of the stones was confirmed in as high as 76% (19/25) of the patients at the second endoscopic intervention 4–28 months after introduction of endoprostheses. These 19 patients were successfully freed from stones by conventional endoscopic means. One of the possible factors that determines the feasibility of stone disintegration is the composition of stones: Brown pigment stones, that are characterized by easily crushable stones, may be more likely to be fragmented with the placement of endoprostheses. A recent report by Johnson et al has emphasized the supplementary use of ursodeoxycholic acid in clearing the ducts (17): All ten patients managed with concomitant ursodeoxycholic acid therapy showed complete or partial clearance of the stone after six months’ biliary endoprosthesis, while in another ten patients who received biliary endoprosthesis alone only one showed stone clearance.

For stones that are too large to remove by conventional endoscopic means, techniques have developed that reduce the size of the stones prior to extraction. Mechanical lithotripsy is simple and readily available, and has been regarded as the next procedure of choice for stones that are resistant to conventional balloons or baskets. For stones that cannot be removed by mechanical lithotripsy, several therapeutic options are currently available, which include electrohydraulic lithotripsy, laser lithotripsy, and extracorporeal shock-wave lithotripsy. With use of electrohydraulic lithotripsy or laser lithotripsy, the success rate for clearing the bile ducts varies from 80 to 88% (18–20). These techniques have been performed under direct visualization of cholangioscopy in order to minimize the risk of bile duct injury. However, cholangioscopy via “mother and baby” dual endoscope systems is technically demanding and requires prolonged manipulation. Percutaneous transhepatic cholangioscopy, although effective, requires risky procedures such as percutaneous liver puncture and dilation of the sinus tract. These problems inherent in performance of cholangioscopy render lithotripsy under direct visualization less feasible for high-risk patients. Use of devices for targeting the lithotripsy probe (i.e., a basket with a central lumen for the probe, a circumferential balloon to center the probe tip, and a three-layer sleeve system) may obviate the necessity of cholangioscopy (19), and thus laser/electrohydraulic lithotripsy under fluoroscopic guidance may become a convenient therapeutic option immediately after mechanical lithotripsy has failed. However, further experience is required to establish the safety of these techniques. Extracorporeal shock-wave lithotripsy has been applied for stones refractory to conventional endoscopic means, and the result from a relatively large series is favorable (21). But, the procedure generally requires general or epidural anesthesia, and the complication rate is not insignificant. These disadvantages of this technique may be unfavorable for high-risk patients. Endoscopic placement of the endoprostheses, being a safe and simple method, should be considered for high-risk patients when initial endoscopic stone removal with mechanical lithotripsy fails, since the technique may offer a chance.
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of subsequent bile duct clearance with minimal invasion.

References


