Original Article

Endoscopic Papillary Large Balloon Dilation for the Retrieval of Bile Duct Stones After Prior Billroth II Gastrectomy

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ABSTRACT

Background/Aims: Endoscopic retrieval of large common bile duct (CBD) stones is often difficult in patients who have undergone Billroth II gastrectomy, as anatomic alterations may present technical barriers to successful cannulation and increase procedure-related complications. Endoscopic papillary large balloon dilation (EPLBD) can be an alternative technique for the removal of difficult stones. Accordingly, the aim of this study was to evaluate the safety and effectiveness of EPLBD for CBD stone extraction in patients with Billroth II gastrectomy. **Materials and Methods:** From July 2006 to November 2011, 30 patients who underwent EPLBD with limited endoscopic sphincterotomy (EPLBD + ES) or EPLBD alone for the treatment of large CBD stones (≥10 mm) after Billroth II gastrectomy were retrospectively reviewed. A large balloon dilator (12–18 mm) was used to dilate the ampullary orifice. **Results:** Selective cannulation was successful in 25 patients (83.3%) with a standard catheter. Of the 30 subjects, EPLBD + ES was performed in 19 and EPLBD alone in 11. The mean bile duct diameter was 17.7 ± 4.3 mm (range, 11–31 mm), and mean size of balloon dilation was 14.5 ± 2.6 mm (range, 12–18 mm). Stone removal was successfully completed in 29 patients (96.7%). Successful stone retrieval during the first session was achieved in 27 patients (90.0%). Two cases (6.7%) of mild pancreatitis responded to conservative treatment, and no perforation or mortality was encountered. **Conclusions:** EPLBD with or without needle knife (NK) sphincterotomy seems to be a safe and feasible modality for CBD stone retrieval in patients with prior Billroth II gastrectomy.

Key Words: Billroth II gastrectomy, endoscopic papillary large balloon dilation, endoscopic sphincterotomy

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Patients with large common bile duct (CBD) stones and associated anatomical difficulties present a challenge to endoscopists despite technical advancements. In patients with an anatomical alteration such as Billroth-II (B-II) gastrectomy, standard endoscopic sphincterotomy (ES) is difficult to perform due to the reversed position of the ampulla.[1] Factors contributing to difficulties in patients with an altered anatomy include a long afferent loop to approach the papilla, a reversed direction to access the major papilla, and deep bile duct cannulation. It is well recognized that access to the major papilla at the end of a long afferent loop using a side-viewing endoscope is relatively difficult. A cap-assisted forward-viewing endoscope can be advocated for B-II anatomy, because it simplifies afferent loop intubation and adjustment to the biliary axis as compared with a side-viewing endoscope.[2,3] However, even after reaching the ampulla and achieving deep cannulation, we frequently encounter difficulties retrieving CBD stones because ES using a pull-type sphincterotome in the 5 o' clock direction is technically demanding in patients with a history of B-II gastrectomy.[4] Therefore, the rate of technical failure can be higher than for normal anatomical patients, and serious complications may be encountered.

Recently, several authors have reported that endoscopic papillary large balloon dilation (EPLBD) offers an alternative in patients with prior B-II gastrectomy because the ampullary opening following EPLBD is so wide that large and rectangular-shaped stones can be removed swiftly.[5-8] As compared with conventional ES, EPLBD is technically easier in patients with B-II gastrectomy. Nevertheless, the potential

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risks of perforation are of particular concern because its mortality is quite high compared with patients with normal anatomy. The aim of this study was to evaluate the safety and feasibility of EPLBD for the retrieval of large CBD stones in patients with a prior B-II gastrectomy.

MATERIALS AND METHODS

Thirty patients with a previous history of B-II gastrectomy that underwent EPLBD combined with limited ES (EPLBD + ES; n = 19) or EPLBD alone (n = 11) for the removal of large bile duct stones (≥10 mm) from July 2006 to November 2011 were retrospectively evaluated. Patients with a prior history of ES were excluded. EPLBD was not indicated in patients with concomitant acute pancreatitis and in young patients (<45 years) who were known to have high risk of acute pancreatitis. All endoscopic retrograde cholangopancreatography (ERCP) procedures were performed using a side-viewing duodenoscope (TJF-240; Olympus Optical Corporation, Tokyo, Japan), with one exception, which was performed using a forward-viewing endoscope. All ERCPs were carried out by experienced endoscopists.

All patients were sedated with midazolam (3-5 mg) and pethidine (25-50 mg) initially, and propofol (10-60 mg) was given intravenously during the procedure when required. Cannulation was achieved using a new ERCP catheter with a straight end. After selective cannulation, EPLBD was performed with or without limited ES. The choice of EPLBD + ES or EPLBD alone was made by endoscopists based on experience. In patients treated by EPLBD + ES, small sphincterotomy was done using NK (Boston Scientific Microvasive, Cork, Ireland) over an indwelling plastic stent (7-10 Fr, Cotton–Leung stents, Wilson–Cook Medical, Winston–Salem, NC, USA) or over a guidewire. The ampulla cutting direction was oriented from the 5 o'clock position upward to the indwelling plastic endoprosthesis or guidewire. The plastic stent or guidewire serves as a buttress to prevent excessive movement of the NK, and thus, avoids perforation or bleeding. For five patients who underwent precutting with NK due to failed cannulation using a standard ERCP catheter, EPLBD was performed without further ES. These patients were allocated to the EPLBD + ES group.

A dilating balloon catheter (CRE balloon, Boston Scientific Microvasive, Cork, Ireland) was inserted along the guidewire and positioned at the midpoint of the balloon across the ampullary orifice [Figure 1]. Dilating balloon catheters of 12-18 mm in diameter were applied accordingly, and ballooning size was adjusted with respect to stone size such that it did not exceed CBD diameter. Balloons were gradually inflated with diluted contrast media until balloon waist disappeared under fluoroscopic guidance. However, if any physical resistance was encountered during dilation, additional inflation was not performed to prevent perforation. Mechanical lithotripsy was attempted when stones were too large to remove intact. If there was any suspicion of incomplete stone removal, a nasobiliary tube (Wilson–Cook., Winston–Salem, NC, USA) or a plastic stent was placed to prevent cholangitis. Complete stone removal was confirmed by cholangiography or using a nasobiliary tube. Patients were thoroughly monitored for any complications, such as perforation, bleeding, or pancreatitis, during and after procedures. Post-ERCP pancreatitis was defined as a serum amylase level exceeding three times the upper normal limit with the development of abdominal pain after ERCP. A serum amylase level exceeding three times the normal upper limit without any abdominal pain was defined as nonspecific hyperamylasemia. Post-ERCP bleeding was classified as major or minor based on amounts of hemorrhage or the need for intervention. Considerable hemorrhage necessitating transfusion and/or intervention was classified as major bleeding and others as minor bleeding. The study was approved by the institutional review board of our hospital.

RESULTS

The baseline characteristics of the 30 patients are described in Table 1. The male-to-female ratio was 4:1 and mean age of the patients was 71.7 ± 8.5 years (range, 56-86 years). Fifteen (50.0%) patients had gallstones, eight patients (27.6%) had periampullary diverticula, and one patient (3.3%) had CBD stricture. Of the associated disease, one patient had chronic renal failure, one ischemic heart disease, one liver cirrhosis, and three cerebral vascular accidents. Mean stone size in the 30 patients was

Table 1: Baseline characteristics of 30 patients

Variable	Total (n=30)
Mean age (years)	71.7±8.5 (56-86)
Sex (male/female)	24:6 (54.7:45.3)
Gallbladder stone	15 (50.0)
Periampullary diverticulum	8 (27.6)
CBD stricture	1 (3.3)
Underlying disease	
Chronic renal failure	1 (3.3)
Ischemic heart disease	1 (3.3)
Liver cirrhosis	1 (3.3)
Cerebrovascular accident	3 (10.0)
CBD stones	
Mean diameter of stone (mm)	13.9±4.1 (10-25)
Number of stones	
1/2/≥3	19/3/8 (63.3/10.0/26.7)
Types of stones	
Brown/black	28/2 (93.3/6.7)
Mean diameter of CBD (mm)	17.7±4.3 (11-31)

CBD: Common bile duct, Values are presented as means±SDs (range) or as numbers (%)

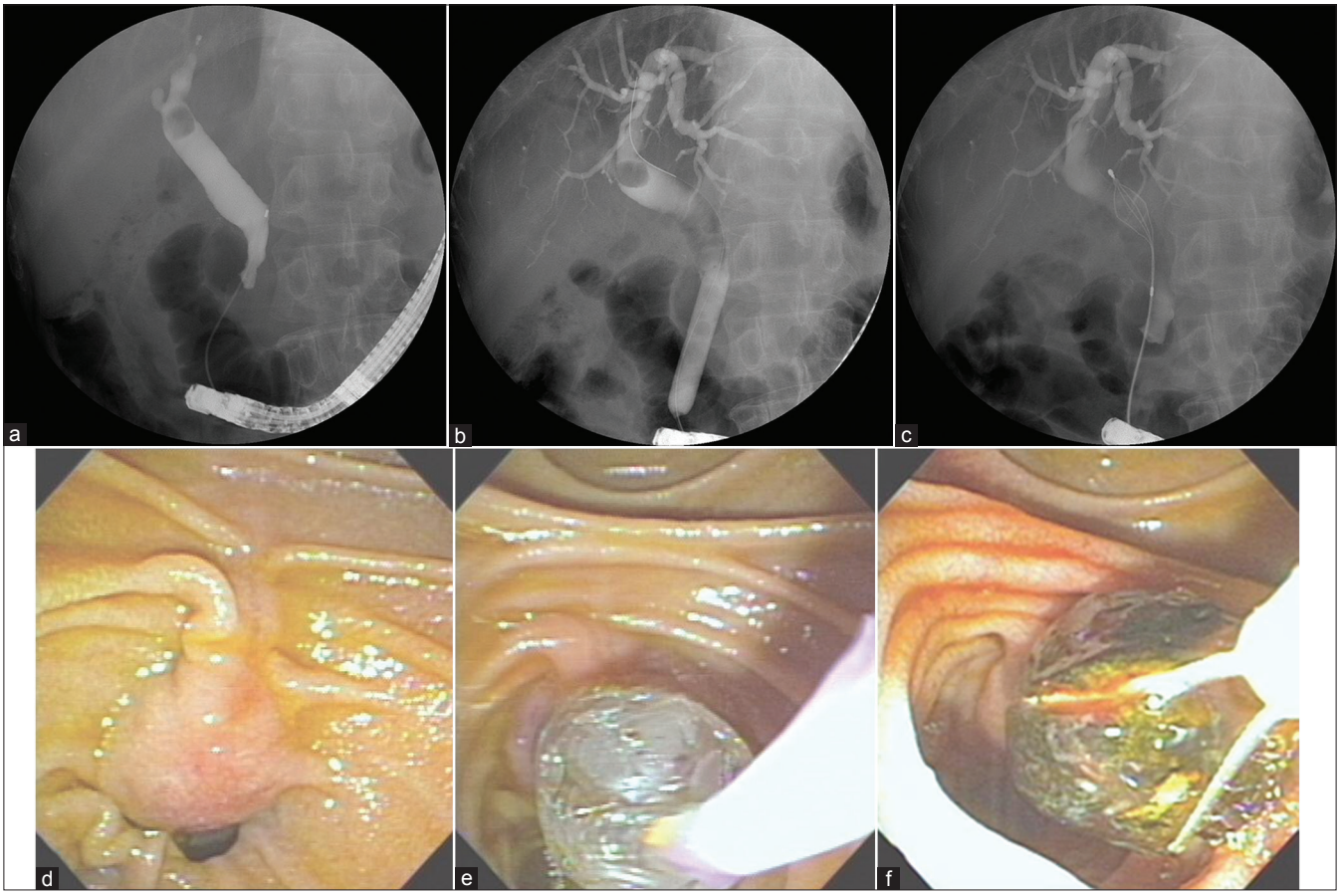

Figure 1: Endoscopic papillary large balloon dilation in a patient with prior Billroth-II gastrectomy (a) Cholangiogram demonstrated a large filling defect in the common bile duct; (b) the notch of balloon disappeared after gradual inflation with diluted contrast media; (c) a large stone was captured by a basket; (d) endoscopic view showed a reversely positioned ampulla abutting a diverticulum; (e) a balloon of 15 mm in size was dilated at the ampullary orifice; (f) a large brown pigment stone was extracted with a basket

13.9 ± 4.1 mm (range, 10-25) and eight patients (26.7%) had three or more bile duct stones. Twenty-eight (93.3%) had brown and two (6.7%) had black pigment stones. Mean bile duct diameter was 17.7 ± 4.3 mm (range, 11-31 years).

ERCP was performed using a side-viewing endoscope in 29 cases (96.7%) and a forward-viewing endoscope in one case (3.3%). Successful cannulation was achieved with a straight catheter in 25 patients (83.3%) and precutting with NK in five patients (16.7%). EPLBD + ES was performed in 19 patients (63.3%) and EPLBD alone in 11 patients (36.7%). Of the 19 patients in the EPLBD + ES group, NK sphincterotomy over a guidewire or indwelling plastic stent was carried out in eight patients (42.1%) and six patients (31.6%), respectively. The mean size of balloon dilation was 14.5 ± 2.6 mm (range, 12-18 mm) and mean duration of ballooning was 37.3 ± 16.0 s (range, 10-80 s) [Table 2].

Table 2: Methods of endoscopic papillary large balloon dilation

Variable	Total (*n*=30)
Type of endoscope	
Side view/forward view	29/1 (96.7/3.3)
EPLBD alone	11 (36.7)
EPLBD+ES	19 (63.3)
NK ES technique	
Guidewire assisted	8 (42.1)
ERBD assisted	6 (31.6)
Precutting	5 (26.3)
Balloon dilation	
Size of dilating balloon (mm)	14.5±2.6 (12-18)
Duration of ballooning (s)	37.3±16.0 (10-60)

EPLBD: Endoscopic papillary large balloon dilation, ES: Endoscopic sphincterotomy, NK ES: Needle knife endoscopic sphincterotomy, ERBD: Endoscopic retrograde biliary drainage. Values are presented as means±SDs (range) or as numbers (%)

Endoscopic stone removal was successfully achieved in 96.7% (29/30) of the study subjects and the remaining one patient underwent operation due to severe distal CBD stricture. Successful stone retrieval was achieved in 27 patients (90.0%) during first endoscopic sessions, in

one (3.3%) during the second session, and in one (3.3%) during the third session. Mechanical lithotripsy was performed in two (6.7%) patients [Table 3].

All procedure-related complications following EPLBD are summarized in Table 4. Nonspecific hyperamylasemia was found in five patients (16.7%). Although two cases (6.7%) of post-ERCP pancreatitis developed, both were mild and recovered conservatively. Of the two (6.7%) clinical bleeding cases, one (3.3%) was major and the other (3.3%) was minor. Major bleeding occurred in a patient with chronic renal failure and 1 pint of blood was transfused after the procedure; the minor bleeding resolved spontaneously. One case (3.3%) of post-ERCP cholangitis responded to intravenous antibiotics. One patient (3.3%) experienced stone recurrence at 9 months and underwent re-ERCP for stone removal. No perforation or in-hospital mortality occurred in our cohort.

DISCUSSION

Stone removal in patients with a history of B-II gastrectomy is relatively troublesome and potentially risky due to a surgically altered anatomy. In patients with surgical alteration, standard ES requires advanced endoscopic skills and is associated with higher complication rates.[9,10] Furthermore, if perforation occurs, re-operation can be difficult and the mortality rate rather high as compared with patients with a normal anatomy. In one study, it was reported that ES in patients with prior B-II gastrectomy had a higher early complication rate (39% vs 22%) and a longer mean procedural time (30 vs 20 min) than patients with a normal anatomy.[1] In particular, use of conventional sphincterotome has some drawbacks in patients with an inverse ampulla anatomy, because it was originally designed to cut the ampulla open in the 11 o'clock direction. To facilitate manipulation of endoscopic accessories and overcome shortcomings in patients with B-II gastrectomy, a variety of clever instruments, such as a rotatable papillotome, an S-shaped sphincterotome, a guidewire sphincterotome, and a needle-knife papillotome, have been attempted.[4-6,8,11,12]

Table 3: Outcome of endoscopic papillary large balloon dilation

Variable	Total (*n*=30) (%)
Overall success rate of stone removal	29 (96.7)
Numbers of stone removal session	
1st session	27 (90.0)
2nd session	1 (3.3)
3rd session	1 (3.3)
Mechanical lithotripsy	2 (6.7)
Operation	1 (3.3)

Table 4: Complications of endoscopic papillary large balloon dilation

Variable	Value (*n*=30) (%)
Hyperamylasemia	5 (16.7)
Pancreatitis	2 (6.7)
Bleeding	2 (6.7)
Major	1 (3.3)
Minor	1 (3.3)
Cholangitis	1 (3.3)
Perforation	0
Mortality	0

In patients with a history of B-II gastrectomy, endoscopic papillary balloon dilation (EPBD) has a shorter procedural time and a lower complication rate than conventional ES and comparable success rates.[1,13] Regardless of the these advantages of conventional EPBD, the ampullary opening is not so large enough; therefore, mechanical lithotripsy is more frequently required for the removal of large sized stones during EPBD.[14-16] Recently, Ersoz *et al*. reported that EPLBD following limited ES (EPLBD + ES) is effective for treating bile duct stones that are difficult to remove in a standard method.[17] Considering the larger size of the ampullary opening, EPLBD + ES can facilitate the extraction of difficult stones in one session and reduce the need for mechanical lithotripsy. After successful cannulation has been accomplished, the remainder of the EPLBD procedure is so simple that it can be performed by inexperienced endoscopists. Recently, several authors have found that EPLBD without ES has a therapeutic efficacy similar to EPLBD + ES in terms of large bile duct stone retrieval regardless of B-II gastrectomy status or normal anatomy.[18] Accordingly, based on safety considerations, EPLBD alone can be regarded as an alternative modality in patients with prior B-II gastrectomy.

A series of studies have reported complete stone removal rates in first sessions ranging from 77% to 100%, and overall stone removal rates of up to 100% in patients with prior B-II gastrectomy.[4-8] In the present study, the overall CBD stone removal and complete stone removal rates for first endoscopic session were 96.7% and 90.0%, respectively, which concur with previous studies.[4-8] Mechanical lithotripsy is an annoying but essential procedure for the removal of large bile duct stones. The wider ampullary opening made during EPLBD can aid the removal of difficult stones and lower the requirement of mechanical lithotripsy.[19] In the present study, mechanical lithotripsy was performed to crush stones in two (6.7%) patients, which also concurs with previous studies (2.5-11.5%).[5,6,8]

Postprocedure pancreatitis, perforation, and bleeding are the most significant complications of EPLBD, and a history

of B-II gastrectomy is one of the crucial patient-related factors attributing to the complications. According to recent reports, ERCP-related complication rates in patients with B-II gastrectomy are 15.0%.[5] However, several studies have reported substantially lower rates of post-ERCP pancreatitis after EPLBD in patients with prior B-II gastrectomy (0-5%).[4,5,7,8] In the present study, only two cases (6.7%) of pancreatitis were observed and both were mild and self-limiting.

Perforation is a life-threatening adverse event associated with EPLBD in patients with B-II gastrectomy, and balloon size and rate of expansion could importantly increase the risk of EPLBD-associated perforation. Forceful expansion of the ampulla can cause perforation, and thus, perforation might be avoided by gradual dilatation to an appropriate size based on consideration of CBD diameter. Furthermore, if any resistance is encountered, dilation should be stopped. Physically, the weakest spot is susceptible to rupture because of the radial force applied during EPLBD, especially in the presence of a distal biliary stricture.[20] Considering the potential risk of EPLBD-related perforation in patients with B-II gastrectomy, conventional EPBD using mechanical lithotripsy might be safer than EPLBD in some cases, because even large soft and muddy stones can be retrieved easily to some extent by conventional EPBD following small ES. Moreover, a blind approach using a side-viewing endoscope might give rise to complicated bowel perforation in cases of sharp angulation. Lately, a few studies have shown that a forward-viewing endoscope can be a better option because it provides easier access to the ampulla and better visualization of the lumen.[2,3] Nevertheless, forward-viewing endoscopes have some disadvantages: (1) its working channel is so narrow that the manipulation of some accessories is restricted, and (2) lack of an elevator can limit the alignment of axis and prevent complete stone retrieval. In the present study, balloon dilation failed in one case (3.3%) due to severe stricture of the distal CBD, and therefore, this case was converted to surgery for the removal of multiple bile duct stones. No patient developed perforation in the present study.[4,5,7]

Bleeding is another critical complication that is possibly related to NK sphincterotomy. This technique is difficult and dangerous in patients with a B-II anatomy due to a reversed biliary axis. In a previous study, it was found that patients with B-II gastrectomy had a higher bleeding rate than patients with a normal anatomy (17% (3/18) vs. 2% (2/87)), which means ES in patients with a B-II anatomy is associated with a higher bleeding risk.[1] However, several articles about EPLBD with or without ES in patients with B-II gastrectomy showed no significant procedure-related bleeding.[4,5,7] In most cases, bleeding was self-limited and controlled by diluted epinephrine injection or by compression using a retrieval balloon. In the present study, there were two cases (6.7%) of clinical bleeding, and both responded to medical therapy with no sequelae.

No in-hospital mortality associated with the procedure was encountered during the present study. In the present study, anatomical alterations, such as previous B-II gastrectomy, did not influence therapeutic outcomes. Furthermore, as mentioned above, EPLBD in patients with a history of B-II gastrectomy was found to require less skillful manipulation, less mechanical lithotripsy, and to have a lower complication rate than conventional ES. Nevertheless, clinical application of this procedure should be done with prudence in selected patients to prevent the procedure-related complications. On top of the early complications presented in the present study, long-term follow up is needed to investigate the late complications of EPLBD, such as stone recurrence, cholangitis, cholecystitis, and papillary stenosis.

In conclusion, EPLBD with or without NK sphincterotomy appears to be a safe and feasible treatment option for CBD stone management in patients with a prior history of B-II gastrectomy. However, large, prospective, randomized controlled, multicenter studies are needed to obtain further clinical results for EPLBD in patients with B-II gastrectomy, because the present study is limited by its small cohort size and its retrospective, single-center design without control.

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