

Endoscopic large-diameter balloon dilation after fistulotomy for the removal of bile duct stones in a difficult cannulation

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Background: When standard methods of biliary cannulation fail, needle-knife fistulotomy may be used. However, large stones cannot be easily extracted through the necessarily smaller opening made when using the fistulotomy technique.

Objective: We report the efficacy and safety of endoscopic large-diameter balloon dilation after fistulotomy for the removal of bile duct stones in patients in whom cannulation is difficult.

Design: A case series.

Setting: A tertiary referral center.

Patients and Interventions: Six patients (6 of 115, 5.2%) with bile duct stones in whom cannulation by the conventional method had failed underwent fistulotomy and large-diameter (12-15 mm) balloon dilation through the fistulotomy tract.

Main Outcome Measurements: Successful biliary cannulation, outcome of therapy, and post-ERCP complications including pancreatitis were recorded.

Results: Biliary cannulation was successful in 6 of 6 patients (100%) with fistulotomy. After endoscopic large-diameter balloon dilation of the fistulotomy tract, stone extraction was successfully performed in 6 of 6 patients. None of the patients developed post-ERCP pancreatitis. One of the 6 patients had minor delayed bleeding, which stopped spontaneously.

Limitations: A small case series, retrospective design, and no control group.

Conclusion: Endoscopic large-diameter balloon dilation through the fistulotomy tract may be a feasible and safe alternative method for the removal of bile duct stones in patients in whom cannulation is difficult.

ERCP is widely used in the diagnosis and treatment of biliary disorders. Successful biliary cannulation is critical for the diagnosis and therapy of biliary disease. Transpapillary cannulation is the preferred technique. However, the success rate of ERCP ranges from 80% to 95%, even among experienced endoscopists.^{1,2} When standard methods of biliary cannulation fail, alternative techniques such as precut papillotomy or fistulotomy with a needle-knife may be used. Fistulotomy with a needle-knife minimizes pancreati-

tis as the most common serious complication because the incision is started a few millimeters above the papillary orifice.^{2,3} However, large stones cannot be easily extracted through the necessarily smaller opening made in the fistulotomy technique.⁴ Ersoz et al⁵ modified sphincterotomy by following it with large-diameter (12-20 mm) balloons, and they reported that bile duct stones that could not be extracted by sphincterotomy could be easily removed with the combination. In this study, we report the efficacy and safety of fistulotomy followed by large-diameter balloon dilation of the fistulotomy tract for the management of patients with choledocholithiasis in whom cannulation is difficult.

Abbreviation: CBD, common bile duct; EPLBD, endoscopic papillary large-balloon dilation.

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PATIENTS AND METHODS

From May 2008 to July 2008, one hundred fifteen patients with bile duct stones were referred for diagnostic

and therapeutic ERCP. Out of a total of 115 patients in whom cannulation was attempted, cannulation by the conventional method failed in 6 patients (5.2%), and these patients underwent fistulotomy and large-diameter balloon dilation through the tract. We analyzed the success rate of cannulation and procedure-related complications. All immediate complications were classified and graded according to the 1991 consensus guidelines.⁶ We performed this retrospective case analysis in accordance with the guidelines of our institutional review board. Possible complications of endoscopic treatment were discussed with the patients and their relatives, and written informed consent was obtained before the endoscopic procedure.

Endoscopic procedures

One endoscopist performed all procedures. Selective cannulation of the common bile duct (CBD) was tried with a transpapillary approach with a conventional cannula and a pull-type sphincterotome. If those attempts failed to yield deep CBD cannulation after more than 20 minutes, and/or the pancreatic duct had been cannulated more than 3 times, a needle-knife fistulotomy was performed in those patients with a high suspicion of biliary tract disease. By using a therapeutic side-viewing videodoscope (TJF-140; Olympus Optical Co, Tokyo, Japan), needle puncture of the bile duct was performed by using a needle-knife (MicroKnife XL, Boston Scientific, Natick, Mass) in the direction of the CBD at about the junction of the upper third and the lower two thirds of the ampullary mound. Without confirming the entrance of the CBD, cutting either upward in a cephalad direction or downward toward the orifice was not performed. After needle puncture of the bile duct, a soft-tipped, 0.025-inch guidewire (Jagwire, Boston Scientific) was advanced in 2- to 3-mm increments to gain access to the CBD after the fistulotomy (Fig. 1A). The guidewire was advanced further into the bile duct, and no contrast medium was injected until deep cannulation with the guidewire had been attained. After deep cannulation with the guidewire was achieved, cholangiogram was attained (Fig. 1B). Three punctures were allowed before the cannulation was considered a failure. After needle puncture of the bile duct, 2 additional 2- to 3-mm incision extensions were made by using the standard double-lumen sphincterotome (Olympus Optical Co, Ltd, Tokyo, Japan) with blended current, proceeding upward at 11-o'clock and 12-o'clock, respectively.

After needle-knife puncture and small incision extension, the fistulotomy tract was dilated with 12-to-15-mm balloon dilatation catheters (Fig. 1C) (CRE balloon dilatation catheter, Boston Scientific). The balloon diameter was selected according to the diameter of the bile duct and the size of the stone. To decrease the risk of perforation, using a balloon with a diameter much larger than that of the bile duct was avoided. The balloon was positioned across

the fistulotomy opening and inflated with diluted contrast medium at a pressure of 3 psi for 30 to 60 seconds under endoscopic and fluoroscopic guidance so that we could observe the gradual disappearance of the waist in the balloon. Once the waist disappeared, the balloon remained inflated for 60 seconds. After large-diameter balloon dilatation, stones were extracted by using a retrieval basket and/or balloon-tipped catheter (Fig. 1D). Mechanical lithotripsy was used when necessary, and a biliary endoprosthesis was inserted in cases of incomplete stone removal.

Observations

Six patients with bile duct stones underwent a total of 11 ERCP examinations. There were 4 men and 2 women, with a median age of 72.5 years (range 56-87 years). The median size of the stones was 16.5 mm (range 8-21 mm). The median number of stones was 2.5 (range 1-4). The median diameter of the bile duct was 17.5 mm (range 11-22 mm). Four of the 6 patients had periampullary diverticula. All patients underwent needle-knife fistulotomy after transpapillary biliary cannulations failed. Biliary cannulation was then successful in 6 of 6 patients (100%). Stone extraction was successful in 6 of 6 patients. In 4 patients, endoscopic papillary large-balloon dilation (EPLBD) and stone removal were deferred until a second session due to a relatively long procedure time and patient irritability. A second session was performed within a week, according to the patients' clinical conditions and laboratory test findings. None of the patients developed post-ERCP pancreatitis. One of the 6 patients had minor delayed bleeding, which stopped spontaneously. The results are summarized in Table 1.

DISCUSSION

Fistulotomy is an effective procedure in gaining access to the bile duct. The overall success rate of fistulotomy was 83% to 96%.⁷⁻⁹ In cases of difficult bile duct access, the fistulotomy technique has certain benefits, including a lower incidence of pancreatitis and absence of aggravating factors of established biliary pancreatitis. Direct mechanical injury to the pancreatic duct orifice from repeated probing of the ampulla can be avoided.³ Chemical, allergic, and hydrostatic injury to the pancreatic duct from inadvertent injection of contrast medium into the pancreatic duct is eliminated by totally avoiding pancreatic duct injections. This is achieved by selective injection into the bile duct only after confirmation of the position of the guidewire in the bile duct, preserving pancreatic flow after the procedure.^{1,10,11}

Theoretically, large stones cannot be easily extracted through the necessarily smaller opening made during the fistulotomy technique. Mavrogiannis et al⁴ showed that larger stones were extracted in the fistulotomy with more difficulty. The success rate of stone extraction was

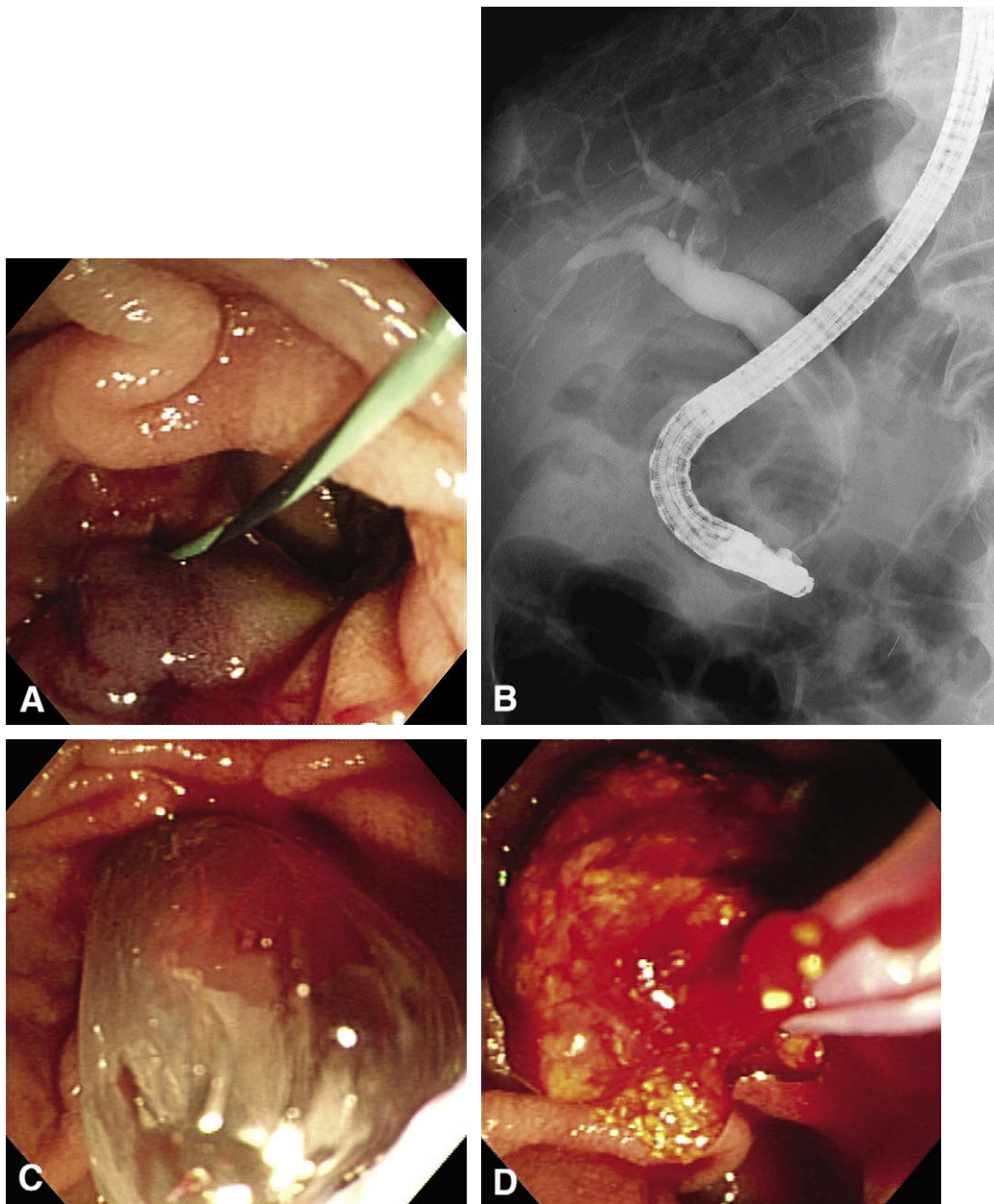


Figure 1. Fistulotomy with large-balloon dilatation. **A**, After needle puncture of the bile duct, a soft-tipped, 0.025-inch guidewire was advanced to gain access to the common bile duct after the fistulotomy. **B**, After deep cannulation with the guidewire was achieved, a cholangiogram was attained. **C**, After needle-knife puncture and small incision extension, the fistulotomy tract was dilated with 12- to 15-mm balloon dilatation catheters according to the diameter of the bile duct and the size of the stones. **D**, After large-diameter balloon dilatation, stones were extracted by using a retrieval basket.

64.2% to 83.3% in the fistulotomy-only technique.⁷ For the removal of large stones through the fistulotomy tract, incision extension should be performed. However, long incision extension downward to the papillary orifice can increase the risk of pancreatitis, and long incision extension upward can increase the risk of perforation. Therefore, we performed large-diameter balloon dilation through the fistulotomy tract without long incision extension upward or downward. In the present study, all bile duct stones were successfully removed without significant complications, including pancreatitis and perforation.

Previous studies on EPLBD showed that complete removal of bile duct stones in 1 session was achieved in 78% to 100% of cases.^{12,13} However, in this study, two thirds of the patients required more than 1 endoscopic session to clear the bile ducts. The reason for this difference of success rate in a single endoscopic session was as follows: all patients in this case series underwent needle-knife fistulotomy after transpapillary biliary cannulations had failed. In 4 patients, EPLBD and stone removal were deferred until a second session due to relatively long procedure time and patient irritability. Complete removal of stones was achieved in

TABLE 1. Results of fistulotomy with large-balloon dilation in cases of difficult bile duct access

	Patient no.					
	1	2	3	4	5	6
Age (y)	56	66	75	87	72	73
Sex	M	M	F	F	M	M
Previous cholecystectomy	No	Yes	No	Yes	No	Yes
Gallbladder stone	Yes	No	Yes	No	Yes	No
Diameter of CBD (mm)	19	15	22	18	11	17
Maximal size of CBD stone (mm)	16 × 13	18 × 12	21 × 21	17 × 15	8 × 8	11 × 12
Number of CBD stones	4	2	3	2	4	1
Periampullary diverticulum	Yes	Yes	Yes	No	Yes	No
Cannulation	Success	Success	Success	Success	Success	Success
Diameter of balloon dilation (mm)	12	12	15	13.5	12	15
Mechanical lithotripsy	Yes	No	Yes	Yes	No	No
Stone extraction	Success	Success	Success	Success	Success	Success
Sessions	2	2	3	2	1	1
Post-ERCP hyperamylasemia	No	No	No	No	No	No
Other complications	No	Delayed minor bleeding	No	No	No	No

CBD, Common bile duct.

3 of those 4 patients at the second session. In 1 patient, clearance of stones was achieved at a third session. Therefore, complete removal of stones was achieved in 5 of 6 patients (83%) after the first EPLBD.

Recently, large-diameter balloon dilation after sphincterotomy has been reported as an effective procedure for removal of bile duct stones.^{14,15} However, in this technique, a potential advantage of endoscopic papillary balloon dilatation over endoscopic sphincterotomy is lost. The biliary sphincter cannot be preserved due to endoscopic sphincterotomy, and the risk of pancreatitis cannot be decreased to an ideal level. In the present study, the risk of pancreatitis was minimized because balloon dilation was performed a long distance from the pancreatic sphincter. In addition, the most important benefit of the present technique is its feasibility in cases of difficult cannulation and difficulty removing bile duct stones.

A potential complication related to large-diameter balloon dilation after sphincterotomy is perforation. Fortunately, in the present study, none of the patients had perforation. Actually, a previous study¹³ showed that only 1 of 103 patients (0.01%) had perforation of the cystic ducts. For the prevention of abrupt rupture of the papillary roof, we performed 2 small incision extensions before the large-diameter balloon dilation.

Another potential complication related to this procedure is bleeding. In the present study, minor delayed bleeding occurred in 1 of 6 patients. The previous study

showed that 1 of 103 patients developed significant bleeding, which was controlled angiographically, and 1 of 103 patients developed moderate bleeding.¹³

The main limitation of the present study is a small case series (n = 6) without a control group. Therefore, large, randomized, controlled, prospective trials comparing this technique with other alternatives should be performed.

In conclusion, therapeutic ERCP with fistulotomy combined with large-diameter balloon dilation may be a feasible and safe alternative method in patients in whom bile duct access is difficult. This result warrants further evaluation of its relative benefits compared with conventional methods.

REFERENCES

1. Abu-Hamda EM, Baron TH, Simmons DT, et al. A retrospective comparison of outcomes using three different precut needle knife techniques for biliary cannulation. *J Clin Gastroenterol* 2005;39:717-21.
2. de Weerth A, Seitz U, Zhong Y, et al. Primary precutting versus conventional over-the-wire sphincterotomy for bile duct access: a prospective randomized study. *Endoscopy* 2006;38:1235-40.
3. Freeman ML, Nelson DB, Sherman S, et al. Complications of endoscopic biliary sphincterotomy. *N Engl J Med* 1996;335:909-18.
4. Mavrogiannis C, Liatsos C, Romanos A, et al. Needle-knife fistulotomy versus needle-knife precut papillotomy for the treatment of common bile duct stones. *Gastrointest Endosc* 1999;50:334-9.
5. Ersoz G, Tekesin O, Ozutemiz AO, et al. Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract. *Gastrointest Endosc* 2003;57:156-9.

6. Cotton PB, Lehman G, Vennes J, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1991;37:383-93.
7. Khatibian M, Sotoudehmanesh R, Ali-Asgari A, et al. Needle-knife fistulotomy versus standard method for cannulation of common bile duct: a randomized controlled trial. *Arch Iran Med* 2008;11:16-20.
8. Recchia S, Coppola F, Ferrari A, et al. Fistulosphincterotomy in the endoscopic approach to biliary tract diseases. *Am J Gastroenterol* 1992;87:1607-9.
9. O'Connor HJ, Bhutta AS, Redmond PL, et al. Suprapapillary fistulosphincterotomy at ERCP: a prospective study. *Endoscopy* 1997;29:266-70.
10. Masci E, Mariani A, Curioni S, et al. Risk factors for pancreatitis following endoscopic retrograde cholangiopancreatography: a meta-analysis. *Endoscopy* 2003;35:830-4.
11. Elta GH, Barnett JL, Wille RT, et al. Pure cut electrocautery current for sphincterotomy causes less post-procedure pancreatitis than blended current. *Gastrointest Endosc* 1998;47:149-53.
12. Minami A, Hirose S, Nomoto T, et al. Small sphincterotomy combined with papillary dilation with large balloon permits retrieval of large stones without mechanical lithotripsy. *World J Gastroenterol* 2007;13:2179-82.
13. Attasaranya S, Cheon YK, Vittal H, et al. Large-diameter biliary orifice balloon dilation to aid in endoscopic bile duct stone removal: a multi-center series. *Gastrointest Endosc* 2008;67:1046-52.
14. Misra SP, Dwivedi M. Large-diameter balloon dilation after endoscopic sphincterotomy for removal of difficult bile duct stones. *Endoscopy* 2008;40:209-13.
15. Heo JH, Kang DH, Jung HJ, et al. Endoscopic sphincterotomy plus large-balloon dilation versus endoscopic sphincterotomy for removal of bile-duct stones. *Gastrointest Endosc* 2007;66:720-6; quiz 768, 771.

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