

Comparison of endoscopic papillary balloon dilatation and endoscopic sphincterotomy for bile duct stones

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Abstract

Endoscopic treatment for bile duct stones is low-invasive

and currently considered as the first choice of the treatment. For the treatment of bile duct stones, papillary treatment is necessary, and the treatments used at the time are broadly classified into two types; endoscopic papillary balloon dilatation where bile duct closing part is dilated with a balloon and endoscopic sphincterotomy (EST) where bile duct closing part is incised. Both procedures have advantages and disadvantages. Golden standard is EST, however, there are patients with difficulty for EST, thus we must select the procedure based on understanding of the characteristics of the procedure, and patient backgrounds.

Key words: Bile duct stones; Endoscopic papillary balloon dilatation; Endoscopic sphincterotomy; Endoscopic retrograde cholangiopancreatography; Post endoscopic retrograde cholangiopancreatography pancreatitis

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Core tip: For the treatment of the bile duct stones, it is necessary to perform papillary treatment, and the treatment used at the time are broadly classified into two groups such as endoscopic papillary balloon dilatation and endoscopic sphincterotomy (EST). Golden standard is EST, however, there are patients with difficulty for EST, thus we must select the procedure based on understanding of the characteristics of the procedure, and patient backgrounds.

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INTRODUCTION

Currently, the treatment for the bile duct stones are widely conducted with endoscopic treatment as the first choice^[1]. Advantages of endoscopic treatment when compared with the surgery lie in that it can cope with promptly even at the emergent time and it is possible to perform the treatment low-invasively with less human power in a short period of time. Percutaneous transhepatic approach exists, too, but I have long time for treatment and am not performed very much because a maneuver is complicated. The papillary treatment conducted at the time includes endoscopic papillary balloon dilatation (EPBD) and endoscopic sphincterotomy (EST). Although EST is the golden standard procedure, there are patients who are indicated for EPBD. This report describes treatment success rate, procedural accidents, long term prognosis, and indication of EPBD and EST for the bile duct stones.

HISTORY OF EPBD AND EST

EPBD is the procedure reported by Staritz *et al.*^[2] in 1982. Then during 1990's Mac Mathuna *et al.*^[3] and Komatsu *et al.*^[4] have reported. However, it has scarcely been used in Western countries because of problems of postoperative pancreatitis, whereas EST has been used for 40 years or longer after reported by Kawai *et al.*^[5] and Classen *et al.*^[6] in 1974, and currently it has become established as the first choice of endoscopic treatment method for bile duct stones all over the world.

INDICATION OF EPBD AND EST

Based on advantages and disadvantages of EPBD and EST, their respective good indication and points to notice are described. Basically, EST is the first choice, however, patients with liver cirrhosis, blood disease, or patients undergoing anticoagulant therapy or dialysis who have bleeding tendency or patients who are treated with Billroth-II method or gastric bypass with Roux en Y Reconstruction and have anatomical difficulty in undergoing EST are good indications of EPBD^[7,8]. On the other hand, in patients who underwent pancreatography which is considered as high risk factor of post-EPBD pancreatitis, indication must be carefully examined^[9]. In using the mechanical crushing tool for a number of stones or giant stones, it becomes necessary to repeatedly insert the basket balloon catheter into the bile duct for lithotomy. In EPBD, the bile duct opening is not so dilated, thus due to papillary edema, it becomes difficult to insert the treatment tool in the early stage, leading to high frequency of the erroneous insertion into the pancreatic duct. It is considered that incidence of

post-EPBD pancreatitis is high in the younger people, however we hesitate to eliminate the papillary function by conducting EST, considering long term prognosis. There is a report of the study including only 5 patients which describes that bile duct stones in the children were safely and effectively treated with EPBD^[10]. If the treatment can be done more safely by device of safer procedure, indication for EPBD may spread.

ACTUAL PROCEDURE OF EPBD AND EST

The difference between EPBD and EST lies in dilation method of the bile duct closing part of the duodenal papilla, one dilates by dilatating with the balloon and the other dilates by incising with a sphincterotome. In EPBD, once the guidewire can be inserted into the bile duct, the balloon catheter is selected by conforming bile duct diameter through this guidewire, and inserted for dilatation, thus easy by far when compared with EST in terms of the procedure. In EPBD, the bile duct opening of the papilla is not cut and dilated as in EST, thus function of sphincter of Oddi is conserved to some degree. However, on the other hand, insertion of a stone harvesting and crushing tool is more difficult than EST because bile duct opening is small. Furthermore stones around 10 mm in size which can be removed in EST without any treatment cannot be removed in EPBD if they are not crushed with the mechanical lithotripsy tool. In EST, incision is conducted by adjusting the position of the scope with the blade of sphincterotome in the direction of 11-12 o'clock. The procedure must be conducted always paying attention to insertion angle, depth, direction of blade, and incising speed of a sphincterotome into the papilla because risk of perforation and bleeding is high differently from balloon dilatation, thus difficulty level of the procedure is high.

TREATMENT RESULTS OF EPBD AND EST

The results of comparison test on EPBD and EST reported up to the present are described (Table 1)^[11-24]. High complete stone removal rate of 90% or greater is obtained by both methods in a number of reports, and based on these results, it can be determined that final treatment success rate is almost the same. On the other hand, as to procedural accidents, there are reports describing that pancreatitis^[18-20,24] was observed in EPBD, whereas bleeding^[19-21] in EST, and each frequency is high. In particular, in multi-center study conducted in United States, death case due to post-EPBD pancreatitis was observed, which led to that EPBD has been scarcely conducted in Western countries^[20]. As the risk factor of post-EPBD pancreatitis, young people, past history of pancreatitis, no dilated bile duct (9 mm or less), use of the mechanical lithotripsy tool, and pancreatography are reported up to the present^[9,25-28]. As the measure

Table 1 Short term treatment results of endoscopic papillary balloon dilatation and endoscopic sphincterotomy

Ref.	Sample size (EPBD/EST)	Indication	Complete stone removal	Early procedural accident (whole)	Pancreatitis	Mild	Moderate	Severe	Cholecystitis	Cholangitis	Bleeding	Perforation	Basket impaction
Minami <i>et al</i> ^[11]	20/20	No limit	100%/100%	10%/10%	10%/10%	-	-	-	-	-	-	-	-
Bergman <i>et al</i> ^[12]	101/101	No limit	89%/91%	17%/24%	6.9%/6.9%	-	-	-	-	-	0%/4.0%	2.0%/1.0%	-
Ochi <i>et al</i> ^[13]	55/55	Diameter < 15 mm, number < 10	98.1%/92.7%	2.0%/5.6%	0%/3.7%	0%/0%	0%/3.7%	0%/0%	-	-	-	0%/1.9%	-
Yasuda <i>et al</i> ^[14]	35/35	No limit	100%/100%	5.7%/8.6%	5.7%/5.7%	5.7%/5.7%	0%/0%	0%/0%	-	-	0%/2.9%	-	-
Arnold <i>et al</i> ^[15]	30/30	Diameter < 20 mm, number < 5	77%/100% ¹	30.0%/16.7%	20%/10%	13.3%/10%	0%/0%	6.7%/0%	-	10%/0%	0%/6.7%	-	-
Natsui <i>et al</i> ^[16]	70/70	No limit	92.9%/98.6%	10.0%/11.4%	5.7%/4.3%	5.7%/4.3%	-	-	-	2.9%/4.3%	0%/2.9%	-	1.4%/0%
Vlavianos <i>et al</i> ^[17]	103/99	No limit	87.4%/86.9%	6.8%/3.0%	4.9%/1.0%	1.9%/0%	1.9%/1.0%	1.0%/0%	-	1.9%/1.0%	-	-	-
Fujita <i>et al</i> ^[18]	138/144	Diameter < 14 mm	99.3%/100%	14.5%/11.8%	10.9%/2.8% ¹	8.7%/2.1%	2.2%/0.7%	9%/0%	2.2%/4.2%	1.4%/4.2%	0%/1.4%	-	0.7%/0.7%
Baron <i>et al</i> ^[19]	552/554	Meta-analysis	94%/96%	10.4%/10.3%	7.4%/4.3% ¹	-	-	-	2.7%/3.6%	-	0%/2.0% ¹	0.4%/0.4%	-
Disario <i>et al</i> ^[20]	117/120	Diameter < 10 mm, number < 4	97.4%/92.5%	17.9%/3.3% ¹	10.3%/0.8% ¹	-	-	5.1%/0%	0%/0.8%	0.9%/0.8%	10.5%/27.0% ¹	0%/0.8%	-
Lin <i>et al</i> ^[21]	51/53	Diameter < 20 mm	94.1%/100%	-	-	-	-	-	-	-	2.0%/26.4% ¹	0%/0.8%	-
Takezawa <i>et al</i> ^[22]	46/45	No limit	100%/100%	0%/0%	-	-	-	-	-	-	-	-	-
Tanaka <i>et al</i> ^[23]	16/16	No limit	100%/100%	18.8%/25.0%	18.8%/18.8%	-	-	-	-	0%/12.5%	-	-	-
Watanabe <i>et al</i> ^[24]	90/90	No limit	86.6%/95.6%	14.4%/3.3% ¹	10.0%/2.2% ¹	8.9%/0%	1.1%/2.2%	-	-	3.3%/0%	1.1%/0%	-	1.1%/0%

¹ $P < 0.05$. EPBD: Endoscopic papillary balloon dilatation; EST: Endoscopic sphincterotomy.

to prevent onset of post-EPBD pancreatitis, intraoperative intravenous drip of isosorbide dinitrate with relaxant effect for the sphincter of Oddi^[29,30], postoperative papillary epinephrine spray to prevent papillary edema^[31], indwelling of pancreatic duct stent^[32] or endoscopic nasobiliary drainage^[33] are attempted and their respective usefulness is reported.

With regard to dilatation pressure and time of the balloon, it has been considered that dilatation at low pressure and short time gives less burden on the papilla and develops less postoperative papillary edema, thus is good for prevention of pancreatitis^[34], however, there appeared a report that longer dilatation time leads to less incidence of pancreatitis^[35,36], which we need to study hereafter.

PAPILLARY FUNCTION OF POST-EPBD AND POST-EST

Sato *et al*^[37] reported after conducting EPBD that significant decrease in bile duct inner pressure, papillary basic pressure, and papillary contraction pressure were observed at 1 wk after EPBD, whereas they were recovered to around the value before EPBD at 1 mo after. Minami *et al*^[11] examined inner pressure and measured papillary function before treatment and at 1 mo after in randomized controlled trial (RCT) comparing EST with EPBD, and reported that a significant decrease was observed in EST, whereas recovery was found without any significant difference in EPBD. Kawabe *et al*^[38] histologically studied the papillary finding of patients who underwent surgery after EPBD

Table 2 Comparison of long term prognosis between endoscopic papillary balloon dilatation and endoscopic sphincterotomy

Ref.	Sample size (EPBD/EST)	Follow-up period	Total	Stone recurrence	Cholangitis	Cholecystitis	Liver abscess	Biliary cancer
Bergman <i>et al</i> ^[12]	101/101	6 mo	18%/23%	7.9%/6.9%	-	1.3%/9.9%	0%/1.0%	-
Ochi <i>et al</i> ^[13]	51/54	Median 23 mo	3.9%/14.8%	3.9%/5.6%	3.9%/3.7%	3.3%/18.5%	-	-
Yasuda <i>et al</i> ^[14]	235/126	Median 37.4/36.3 mo	-	10%/14%	0%/3.2%	2.0%/8.8%	-	-
Natsui <i>et al</i> ^[16]	68/69	Median 30 mo	5.9%/8.7%	4.4%/4.3%	-	3.6%/7.9%	-	-
Vlavianos <i>et al</i> ^[17]	103 /99	12 mo	11.7%/15.2%	1.9%/3.0%	1.9%/1.0%	1.9%/2.0%	-	-
Lin <i>et al</i> ^[21]	51/53	Median 16 mo	-	5.9%/7.5%	-	-	-	-
Yasuda <i>et al</i> ^[51]	138 /144	Median 6.7 yr	10.1%/25.0% ¹	7.8%/17.4% ¹	0%/2.8%	5.5%/8.3%	0%/1.4%	0%/0.7%

¹P < 0.05. EPBD: Endoscopic papillary balloon dilatation; EST: Endoscopic sphincterotomy.

(2-63 wk after EPBD), and reported that breakage of the sphincter was found only in 1 patient at 3 wk after EPBD, and EPBD does not affect the papillary function. According to the above reports, it seems certain that in EPBD the papillary function is recovered in the comparatively early stage in most of patients. On the other hand, as to the report on the papilla and bile duct inner pressure after conducting EST, there are many reports of short term follow up whereas long term follow up is less. Ponce *et al*^[39] reported that papillary basic pressure disappeared immediately after EST, and bile duct inner pressure is also decreased, however, papillary basic pressure partly remains in some patients, which is considered to be related to incision length. Geenen *et al*^[40] conducted papillary inner pressure examination at 1 and 2 years after EST and reported that although bile duct inner pressure and papillary basic pressure disappeared even at 2 years after, height of papillary contracting wave was recovered at 2 years after, showing no significant difference when compared with before EST. According to report of Bergman *et al*^[41] on the study at 15-17 years after conducting EST, papillary basic pressure disappeared and papillary contracting wave disappeared in 75% of patients. Study by Sugiyama *et al*^[42] revealed that incision length by EST is contracted during the course and becomes the length of about 70% at 5 years after, and improvement of papillary function to some degree is expected in the long term. Although papillary basic pressure disappears in a large number of patients after EST, in part of patients with short incision length, it is presumed that remaining or recovery of papillary contracting wave is expected.

LONG TERM PROGNOSIS OF EPBD AND EST

As for long term prognosis after EPBD, Tsujino *et al*^[43] conducted the investigation including 837 patients with mean follow-up period of 4.4 years and reported that

stone recurrence was found in 8.8%, and cholecystitis was in 3.4%, whereas, as to long term prognosis after EST, it is reported that stone recurrence was found in 8.0%-12.3% and cholecystitis in 4.0%-6.7% during mean follow-up period of 6.2-15 years^[44-50]. These are reports by a single procedure. There are some comparative control studies on EPBD and EST (Table 2)^[12-14,16,17,21]. Bergman *et al*^[12] compared late complications until 6 mo after in RCT, and reported that cholecystitis occurred in 1.3% after EPBD, whereas 9.9% after EST, showing significant low rate in EPBD group. Ochi *et al*^[13] also reported that cholecystitis occurred in 3.3% after EPBD and 18.5% after EST during mean follow-up period of 23 mo, and if limited to patients with cholecyst conserved, its frequency was 4.5%, and 29.4%, respectively, showing significant difference^[13]. Yasuda *et al*^[14] conducted retrospective study on late complications in EST and EPBD, and reported that stone recurrence/cholangitis occurred in 10.0% for EPBD, and 17.2% for EST and cholecystitis occurred in 2.0% for EPBD, and 8.8% for EST during median follow-up period of about 3 years (12-67 mo), showing incidence was high in EST with significant difference. Furthermore, Yasuda *et al*^[51] reported the results of long term follow-up in patients of RCT^[18] studying the short term results of EPBD and EST^[51]. According to this, accumulated recurrence rate of stone recurrence/cholangitis was significantly higher after EST during median follow-up period of 6.7 years. These results suggest that whether papillary function can be conserved or not after treatment of the bile duct stones affects long term prognosis, particularly stone recurrence. In considering long term prognosis, a possibility is concerned that inflammation of the bile duct mucosa developed by back-flow of duodenal juice into the bile duct for a long time causes onset of cancer, particularly in patients who underwent EST. However, such a concern is denied by two population-based studies, and actually incidence of biliary cancer is as low as 0%-0.6% in the follow-up of mean 8-14 years after EST. Even in the follow-up of mean 4.4-9.3 years after EPBD, its incidence is

as low as 0%-0.2%, thus the relation between both papillary treatments and onset of biliary cancer may be negative^[52,53].

CONCLUSION

For the treatment of bile duct stones, it is necessary to conduct papillary treatment, and the treatment used at the time is broadly classified into two types; EPBD and EST. Golden standard is EST, however, since there are patients difficult in conducting EST, it is necessary to select the procedure based on understanding of the characteristics of the procedure and patients background.

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