Original Paper

# Comparison Between Endoscopic Biliary Stenting and Nasobiliary Drainage in Patients with Acute Cholangitis due to Choledocholithiasis: Is Endoscopic Biliary Stenting Useful?

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**Key Words:** Acute cholangitis, choledocholithiasis, endoscopic nasobiliary drainage, endoscopic biliary stent, meal intake rate.

## ABSTRACT

**Background/Aims:** To clarify whether or not use of an endoscopic biliary stenting (EBS) is superior to endoscopic nasobiliary drainage (ENBD) in cases of acute cholangitis due to choledocholithiasis. **Methodology:** Of 447 patients with choledocholithiasis who were treated in the Department of Gastroenterology, Fukuoka University Chikushi Hospital between January 1994 and September 2006, the subjects were 99 moderate acute cholangitis patients who underwent endoscopic drainage as initial treatment. Clinical efficacy, complications and patient satisfaction (meal intake rete) were investigated in the EBS group (67 patients) and the ENBD group (32 patients). **Results:** There were no significant differences in the improvement in inflammation, total bilirubin, or biliary enzymes between the EBS and ENBD groups. Catheter occlusion was seen in three patients (4%) in the EBS group, and the catheter was self-extracted by three patients (10%) in the ENBD group. **Conclusion:** In moderate acute cholangitis due to choledocholithisis, the treatment efficacy and safety of EBS are equal to those of ENBD, and EBS appears to be a better choice in elderly patients in particular.

## INTRODUCTION

Biliary drainage is very important in acute suppurative cholangitis, and a patient's general condition can deteriorate rapidly, especially in cases of severe cholangitis, often leading to an unfortunate outcome unless adequate biliary drainage is done promptly (1–3). The types of biliary drainage are endoscopic drainage, percutaneous transhepatic drainage, and open drainage. There are no randomized, controlled studies (RCTs) comparing endoscopic drainage and percutaneous transhepatic drainage, and no definitive conclusion has been reached as to which should be the first choice. However, many reports have stated that endoscopic treatment should be preferred in cases when an endoscopic approach is possible since it is associated with fewer serious complications, such as intraperitoneal hemorrhage or bileperitonitis, and significantly shorter hospital stays (4–6). Endoscopic drainage procedures include EBS and ENBD. In the Tokyo Guidelines for acute cholangitis it is said that both choices are good (7), but there are few RCTs comparing EBS and ENBD or investigations of the effects of endoscopic sphincterotomy (EST) performed prior to EBS or ENBD (8-11). According to published reports, EBS and ENBD have equal biliary decompression effects, but the catheter sizes in EBS and ENBD were not uniform, and acute cholangitis from malignant tumors was also included in the published studies. In this study, we retrospectively assessed whether or not EBS is safe and beneficial for patients with moderate acute cholangitis due to choledocholithiasis.

## METHODOLOGY

Of a cohort of 447 consecutive patients with choledocholithiasis treated in our hospital department between January 1994 and September 2006, 343 patients were diagnosed with acute cholangitis, of whom 117 had moderate acute cholangitis according to the Tokyo Guidelines for acute cholangitis (12). Of these 117 patients, two had concomitant biliary cancer, eight had undergone endoscopic papillary balloon dilation (EPBD) (13), three had undergone percutaneous transhepatic biliary drainage (PTBD), and seven had undergone EST only. These patients were excluded, leaving 97 patients who had undergone endoscopic biliary drainage (EBD; ENBD group, 30 patients; EBS group, 67 patients) as subjects. The patients were treated with ENBD from January 1994 to 2002 and with EBS from 2003 to 2006. The For ENBD, a 7-F pigtail type nasal biliary drainage tube (PBD-21Z; Olympus Medical Systems Corp., Tokyo, Japan) was used. For EBS, a 7-F straight type biliary stent tube (RX Biliary Stent; Boston Scientific Japan Corp., Tokyo Japan) was used. All patients received systemic antibiotics for three days as a rule, and sedation with diazepam was given as needed (14, 15). In patients with a tendency to bleed and patients with restlessness, EBD was done without EST during the initial treatment.

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**TABLE 1.** Comparison of clinical background characteristics between the endoscopic nasobiliary group and the endoscopic biliary stent group (means ± SD).

| Factor | n | ENBD | n | EBS | P value |
|---|---|---|---|---|---|
| Age (years) | 30 | 66 ± 14 | 67 | 69 ± 15 | 0.585 |
| Gender | | | | | 0.186 |
| Male | 20 | -67% | 34 | -51% | |
| Female | 10 | -33% | 33 | -49% | |
| Pancreatitis due to choledocholithiasis | | | | | 0.976 |
| Positive | 5 | -17% | 11 | -16% | |
| Negative | 25 | -83% | 56 | -84% | |
| Parapapillary diverticulua | | | | | 0.258 |
| Positive | 12 | -40% | 19 | -28% | |
| Negative | 18 | -60% | 48 | -72% | |
| Diameter of common bile duct (mm) | 30 | 15 ± 5 | 67 | 13 ± 5 | 0.040 |
| Diameter of choledocolith (mm) | 30 | 15 ± 8 | 67 | 12 ± 8 | 0.020 |
| Number of choledocholiths | | | | | 0.638 |
| 1 | 11 | -37% | 20 | -30% | |
| 2 | 19 | -63% | 47 | -70% | |
| WBC (/L) * | 30 | 9740 ± 6656 | 67 | 9986 ± 5616 | 0.681 |
| PLT (104/L)* | 30 | 21.9 ± 9.0 | 65 | 18.5 ± 8.2 | 0.140 |
| CRP (mg/dL)* | 30 | 6.2 ± 5.8 | 66 | 6.8 ± 7.4 | 0.675 |
| Alb (mg/dL)* | 29 | 3.8 ± 5.8 | 65 | 3.6 ± 7.3 | 0.192 |
| T.Bil (mg/dL)* | 30 | 6.6 ± 5.0 | 67 | 5.5 ± 3.3 | 0.386 |
| AST (IU/L)* | 30 | 307 ± 351 | 67 | 256 ± 264 | 0.935 |
| ALT (IU/L)* | 30 | 355 ± 430 | 67 | 264 ± 208 | 0.788 |
| ALP (IU/L)* | 30 | 1151 ± 807 | 67 | 992 ± 1051 | 0.062 |
| r-GTP (IU/L)* | 30 | 641 ± 468 | 67 | 538 ± 378 | 0.380 |
| Receiving antiplatelet or anticoagulant therapy | | | | | 1.000 |
| Positive | 0 | 0 | 2 | -3% | |
| Negative | 30 | -100% | 65 | -97% | |
| Post-EBD pancreatitis | | | | | 1.000 |
| Positive | 0 | 0 | 2 | -3% | |
| Negative | 30 | -100% | 65 | -97% | |
| EST at the time of EBD | | | | | 1.000 |
| Positive | 8 | -27% | 18 | -27% | |
| Negative | 22 | -73% | 49 | -73% | |
| Post-EST pancreatitis | | | | | 1.000 |
| Positive | 0 | 0 | 1 | -6% | |
| Negative | 8 | -100% | 17 | -94% | |
| Post-EST hemorrhage | | | | | 1.000 |
| Positive | 0 | 0 | 2 | -11% | |
| Negative | 8 | -100% | 16 | -89% | |
| Meal intake rate (%) | 30 | 52 ± 43 | 62 | 75 ± 35 | 0.009 |

*: At the time of EBD.

**TABLE 2.** Comparison of clinical outcomes between the endoscopic nasobiliary group and the endoscopic biliary stent group (means ± SD).

| Factor | n | ENBD | n | EBS | P value |
|---|---|---|---|---|---|
| WBC (/μL)* | 30 | 4120 ± 6521 | 62 | 5030 ± 5300 | 0.236 |
| PLT (´104/μL)* | 30 | -4.2 ± 8.4 | 62 | -4.6 ± 7.1 | 0.927 |
| CRP (mg/dL)* | 30 | 5.0 ± 5.8 | 62 | 4.7 ± 6.8 | 0.963 |
| Alb (mg/dL)* | 22 | 0.33 ± 0.38 | 50 | 0.26 ± 0.52 | 0.620 |
| T.Bil (mg/dL)* | 29 | 3.7 ± 3.9 | 62 | 3.9 ± 3.1 | 0.409 |
| AST (IU/L)* | 29 | 211 ± 335 | 63 | 209 ± 277 | 0.759 |
| ALT (IU/L)* | 29 | 177 ± 244 | 63 | 186 ± 189 | 0.430 |
| ALP (IU/L)* | 28 | 435 ± 478 | 60 | 493 ± 1039 | 0.417 |
| r-GTP (IU/L)* | 27 | 312 ± 279 | 62 | 293 ± 253 | 0.929 |
| Number of days to alleviate fever | 15 | 2.3 ± 2.1 | 40 | 2.3 ± 2.8 | 0.338 |

Laboratory parameter (before EBD – 7 days after EBD).

The basic incision for EST was a medium incision 916). The ENBD tubes were not washed out as a rule, although when occlusion was suspected, they were washed out with a small amount of physiological saline.

**Factors analyzed**

1. In both the ENBD and EBS groups, the following factors were analyzed: clinical background [age, sex, the presence/absence of cholecystolithiasis, the presence/absence of pancreatitis due to choledocholithiasis, the presence/absence of parapapillary diverticula, diameter of the common bile duct (mm), diameter of the choledocholith (mm), number of choledocholiths, WBC (/μL), platelet count (PLT; ×104/μL), CRP (mg/dL), total bilirubin (T. Bil; mg/dL), AST (IU/L), ALT (IU/L), ALP (IU/L), r-GTP (IU/L) at the time of EBD], the presence/absence of receiving antiplatelet or anticoagulant therapy, the presence/absence of post-EBD pancreatitis, the presence/absence of EST at the time of EBD, the presence/absence of post-EST pancreatitis, the presence/absence of post-EST hemorrhage, and the meal intake rate (%).

2. Factors that were considered to be related to the effects of EBD included improved laboratory parameters [WBC (/μL), PLT (×104/μL), CRP (mg/dL), Alb (mg/dL), T. Bil (mg/dL), AST (IU/L), ALT (IU/L), ALP (IU/L), r-GTP (IU/L): before EBD – 7 days after EBD ], and time from EBD until resolution of fever (<37°C).

3. Factors that were considered to be related to the mean rate of meal intake during 7 days after EBD included age, gender, the presence/absence of pancreatitis due to choledocholithiasis, diameter of the common bile duct (mm), diameter of the choledocholith (mm), number of choledocholiths, WBC (/μL), PLT (×104/μL),CRP (mg/dL), T. Bil (mg/dL), AST (IU/L), ALT (IU/L), ALP (IU/L), r-GTP (IU/L), the presence/absence of receiving antiplatelet or anticoagulant therapy, the presence/absence of EST at the time of EBD, the presence/absence of procedure-related pancreatitis, and EBD (ENBD vs. EBS).

Procedure-related pancreatitis was defined as abdominal pain persisting for at least 24 h after the ERCP and associated with an elevation of the serum amylase level to at least three times the upper limit of normal at 18 h after ERCP15, (17). Post-EST hemorrhage was defined as any of the following conditions: 1) appearance of tarry stool; 2) decrease in hemoglobin by 2 mg/dL or more; 3) necessity for blood transfusion; and 4) hemostatic treatments including heat probe (18). The meal intake rate was used as an indicator of patient satisfaction. The mean meal intake rate was calculated from the meal intake rate for three meals (breakfast, lunch, and dinner) from Day 1 to Day 7 after EBD, according to inpatient records.

**Statistical Analysis**

In both the ENBD and EBS groups, the $\chi^2$ and Fisher's exact tests were used for comparisons of categorical data. All continuous data values were expressed as means ± SD. Differences in the mean values were examined by the Mann-Whitney U test.

The relationships between the rate of meal intake and age, sex, the presence/absence of cholecystolithiasis, pancreatitis due to choledocholithiasis, parapapillary diverticula, diameter of the common bile duct, diameter of the choledocholith, number of choledocholiths, WBC, PLT, CRP, T. Bil, AST, ALT, ALP, r-GTP, receiving antiplatelet or anticoagulant therapy, EST at the time of EBD, procedure-related pancreatitis, post-EST hemorrhage, and EBD (ENBD vs. EBS) were investigated by simple regression analysis. Multivariate regression analysis was conducted on the factors that may have affected the rate of meal intake according to the findings of univariate analysis using simple regression analysis. A forward selection method was used for variable selection, and analyses were conducted using stentry ($P$ = 0.20) and slstay ($P$ = 0.25)**.** Statistical significance was defined as a $P$-value <0.05. The software used for the statistical analysis was PASW Statistics 17 for Windows.

**RESULTS**

1. Of the clinical background characteristics, there were no significant differences in age, gender, the presence/absence of pancreatitis due to choledocholithiasis, the presence/absence of parapapillary diverticula, number of choledocholiths, administration of antithrombotic agents, presence/absence of post-EBD pancreatitis, presence/absence of EST at the time of EBD, the presence/absence of post-EST pancreatitis, presence/absence of post-EST hemorrhage, or laboratory parameters before EBD, but the diameter of the common bile duct, the diameter of choledocholiths and meal intake rate were greater in the ENBD group than in the EBS group ($P$ = 0.040, $P$ = 0.020, and $P$ = 0.009: **Table 1**). All cases of procedure-related pancreatitis were mild (17).

2. There were no significant differences in the levels of improvement in WBC, PLT, CRP, T. Bil, AST, ALT, ALP, and γ-GTP or decrease in Alb during the first week after drainage. The number of patients with fever at the time of admission was 14 in the ENBD group and 40 in the EBS group. The mean time until resolution of the fever was 2.3 days in both groups, with no significant differ-

ence (**Table 2**).

3. The meal intake rate could be investigated in 30 patients (100%) in the ENBD group and 62 patients (93%) in the EBS group. On simple regression analysis, the factors significantly related to the mean meal intake rate from Day 1 to Day 7 after EBD were EBS ($P$ = 0.008), EST ($P$ = 0.029), and CRP level ($P$ = 0.030). That is, the meal intake rate was higher in the EBS group, patients who underwent EST, and patients with low CRP levels. On multiple regression analysis, EBS ($P$ = 0.002), CRP ($P$ = 0.024), and procedure-related pancreatitis ($P$ = 0.034) were significant independent factors (**Tables 3, 4**). That is, the meal intake rate was higher in the EBS group and lower in patients with procedure-related pancreatitis and patients with high CRP levels.

4. In the ENBD group, 3 of the 30 patients (10%) pulled out their ENBD catheter, 2 of whom were very old (≥85 years old). There was no catheter occlusion or migration. In the EBS group, occlusion occurred in 3 of the 67 patients (4%). One of these patients had purulent bile in the biliary tract, and the another one had a giant parapapillary diverticulum. There was no catheter migration. The incidence of complications was not significantly different between the groups (**Table 5**).

**TABLE 3.** Univariate analysis for predictive factors associated with the meal intake rate during 7 days after EBD (means ± SD).

| Factor | n | Meal intake rate (%) | r | P value |
|---|---|---|---|---|
| Age (years) | 92 | 68 ± 39 | -0.096 | 0.269 |
| Gender | | | -0.215 | 0.130 |
| Male | 54 | 73 ± 39 | | |
| Female | 38 | 60 ± 38 | | |
| Pancreatitis due to choledocholithiasis | | | 0.080 | 0.572 |
| Positive | 14 | 62 ± 39 | | |
| Negative | 78 | 69 ± 39 | | |
| Diameter of common bile duct (mm) | 92 | 68 ± 39 | -0.156 | 0.089 |
| Diameter of choledocolith (mm) | 92 | 68 ± 39 | -0.124 | 0.926 |
| Number of choledocholiths | | | 0.088 | 0.270 |
| 1 | 31 | 61 ± 42 | | |
| ≥2 | 61 | 71 ± 37 | | |
| WBC (/μL)* | 92 | 68 ± 39 | -0.041 | 0.127 |
| PLT (´104/μL)* | 92 | 68 ± 39 | 0.026 | 0.591 |
| CRP (mg/dL)* | 92 | 68 ± 39 | -0.140 | 0.030 |
| T.Bil (mg/dL)* | 92 | 68 ± 39 | 0.020 | 0.653 |
| AST (IU/L)* | 92 | 68 ± 39 | 0.124 | 0.842 |
| ALT (IU/L)* | 92 | 68 ± 39 | 0.166 | 0.459 |
| ALP (IU/L)* | 92 | 68 ± 39 | -0.204 | 0.385 |
| r-GTP (IU/L)* | 92 | 68 ± 39 | 0.104 | 0.619 |
| Receiving antiplatelet or anticoagulant therapy | | | -0.144 | 0.237 |
| Positive | 2 | 100 ± 0 | | |
| Negative | 90 | 67 ± 39 | | |
| EST at the time of EBD | | | -0.234 | 0.029 |
| Positive | 24 | 83 ± 31 | | |
| Negative | 68 | 62 ± 40 | | |
| Procedure-related pancreatitis | | | 0.178 | 0.053 |
| Positive | 2 | 15 ± 21 | | |
| Negative | 90 | 69 ± 39 | | |
| EBD | | | 0.242 | 0.008 |
| ENBD | 30 | 52 ± 43 | | |
| EBS | 62 | 75 ± 35 | | |

*: At the time of EBD.

## DISCUSSION

ENBD and ERBD (EBS) are widely used for biliary decompression in acute cholangitis. ENBD was established by Wurbs and Classen (19) in 1977, and its utility has also been reported in the world (1-3, 11). EBS was developed by Sooehendra et al. (20) in 1979 and is in widespread use today. Reports to date have shown no significant differences between the two in comparisons of success rate, incidence of complications, and drainage effect, and both are considered to be good choices for acute cholangitis (7-11). In previous reports, however, the catheter size in ENBD and EBS was not uniform, and cases of acute cholangitis due to malignant tumor were also included. The subjects in the present study were patients with moderate acute cholangitis due to choledocholithiasis, and patients with concomitant biliary tract malignancies were excluded. The catheter diameter was the same (7-F) for ENBD and EBS. The diameter of the common bile duct and the diameter of the choledocholith were larger in the ENBD group than in the EBS group, but there were no significant differences in the proportion of combination EST or other clinical background factors. A comparison of improvement in blood biochemistry tests and time until resolution of fever from before EBD to seven days after EBD showed no significant differences between the two groups.

The discomfort of patients with transnasally placed ENBD is significant, and problems such as self-extraction of the ENBD catheter by the patient are often seen (9-11). Lee et al. conducted a questionnaire survey of ENBD and ERBD (EBS) patients in which discomfort was rated numerically, and they reported that discomfort was greater in the ENBD group (9). In the present study, a questionnaire survey of patients was not conducted, but the meal intake rate was used as an indicator of patient satisfaction. Daily caloric intake was not calculated; instead, given that the amount of food provided to individual patients differs, the mean meal intake rate from Day 1 to Day 7 after EBD was investigated. On multivariate analysis, significant independent factors related to the meal intake rate were EBS, CRP level, and procedure-related pancreatitis. As mentioned above, there were no significant differences between the groups in the biliary decompression effect or improvement in inflammation. Therefore, the meal intake rate is thought to have been higher in the EBS group than in the ENBD group because the EBS group had less discomfort. With respect to nutritional status, the decrease in the post-EBD serum albumin level was not significantly different between the two groups, but this was probably because EBD was done for a short period. It is thought that patients with high CRP levels did not have sufficient meal intake because there was insufficient improvement in acute cholangitis even after EBD.

**TABLE 4.** Multiple regression analysis for factors associated with the meal intake rate.

| Factor | β | Standardized regression coefficient | t value | P value | R2 |
|---|---|---|---|---|---|
| Constant | -7.744 | | -1.410 | 0.162 | |
| EBS/ENBD | 2.566 | 0.310 | 3.189 | 0.002 | 0.075 |
| CRP | -1.26 | -0.224 | -2.298 | 0.024 | 0.051 |
| Procedure-related pancreatitis | 5.599 | 0.211 | 2.157 | 0.034 | 0.041 |

**TABLE 5.** Complications in the endoscopic nasobiliary group and the endoscopic biliary stent group.

| Factor | ENBD | EBS | P value |
|---|---|---|---|
| Pulled out catheter | 3/30 (10%) | 0 | 0.69 |
| Catheter obstruction | 0 | 3/67 (4%) | |
| Catheter migration | 0 | 0 | |

Patients who developed procedure-related pancreatitis abstained from food even after EBD because of abdominal and back pain due to pancreatitis.

ENBD is an external biliary drainage procedure. With ENBD, the catheter can be washed out, and bile cultures can be done, but bodily fluids are lost and bile does not flow into the intestine. Thus, there is the possibility that lipid digestion and absorption disorders and motility disorders of the intestine will appear during fasting (12). In contrast, EBS is an internal drainage procedure that may lead to the prevention of endotoxemia, since increases in intestinal bacteria and damage to the intestinal mucosa are less likely to occur (21). With long-term placement in ENBD or EBS, spontaneous migration of the tube is often seen, but in the present study, spontaneous migration did not occur in any cases because of the short placement time of one week. In the ENBD group, there were no cases of catheter occlusion and no cases in which the catheter was washed out, but in the EBS group, catheter occlusion was seen in 4% of patients. In contrast, the catheter was self-extracted by the patient in 10% of cases in the ENBD group, of whom about 70% was very old patients, similar to previous reports (8-11). The incidence of complications was lower in the EBS group than in the ENBD group, although the difference was not statistically significant. The reason that patients removed their catheters was discomfort in the nasal region, and as mentioned above, this discomfort is thought to have affected the meal intake rate.

In the present study, no patients died from moderate acute cholangitis. There was no significant difference in the incidence of procedure-related complications between the ENBD and EBS groups. Overall, post-EST bleeding was 8% and post-EST pancreatitis was 4%, similar to previous reports (17). Park et al. (11) found a significant difference in the incidence of hyperamylasemia between two groups with differences in the incidence of EST and the size of catheters. Hyperamylasemia was not investigated in the present study, but similar to three previous RCTs, (9-11) there was no significant difference in the incidence of procedure-related pancreatitis between the two groups, and its pancreatitis was mild in both cases in which it occurred. In addition, the rate of pancreatitis was not affected by the conduction of EST together with EBD. The reasons for this are thought to be that the catheter diameter was the same in both groups, the bile duct and pancreatic duct openings were separated because EST was generally done with a medium incision, and EST was done by endoscopists with more than 10 years of experience.

In conclusion, judging from the biliary decompression effect, the incidence of procedure-related complications, and the meal intake rate (patient satisfaction) in the ENBD and EBS groups, EBS would seem to be the better choice in moderate acute cholangitis due to choledocholithiasis, especially in older patients.

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