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Feasibility of a novel 5F plastic stent in endoscopic transpapillary gallbladder drainage for acute cholecystitis

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Key words
Pancreatobiliary (ERCP/PTCD), Stones, ERC topics

received 5.8.2024
accepted after revision 7.11.2024
accepted manuscript online 11.11.2024

Bibliography
Endosc Int Open 2025; 13: a24657130
DOI 10.1055/a-2465-7130
ISSN 2364-3722

Georg Thieme Verlag KG, Oswald-Hesse-Straße 50, 70469 Stuttgart, Germany

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ABSTRACT

Background and study aims Many reports have demonstrated the efficacy of endoscopic transpapillary gallbladder stenting (EGBS) for acute cholecystitis (AC), most of which have traditionally used a 7F plastic stent. The study aim was to evaluate the efficacy of a novel 5F plastic stent in EGBS for AC.

Patients and methods We designed a retrospective study that compared the outcomes between 7F and 5F stents in patients undergoing EGBS. Among 147 patients who underwent endoscopic transpapillary gallbladder drainage for AC between January 2019 and July 2023, 104 who underwent EGBS using a 7F (n = 53) or 5F (n = 51) plastic stent were included in the analysis.

Results The technical success rate for EGBS, clinical success rate for AC, and early adverse events (AEs) rate in the 7F and 5F groups were 92.5% vs 100%, 100% vs 98.0%, and 5.7% vs 3.9%, respectively, with no significant differences. However, only in the 7F group, four patients failed stent insertion and three patients developed postprocedure pancreatitis. Furthermore, incidence of hyperamylasemia was lower in the 5F group (24.5% vs 9.8%, P = 0.047). The late AE rate did not differ significantly between the 7F and 5F groups (14.3% vs 10.0%). The median time to late AE was 238 days for the 7F group and 187 days for the 5F group, with no significant difference.

Conclusions A 5F stent can provide outcomes comparable to those of a 7F stent and help prevent hyperamylasemia.

Introduction

Although cholecystectomy is the standard treatment for acute cholecystitis (AC) [1], surgery is unsuitable for some patients because of comorbidities. In such patients, percutaneous transhepatic gallbladder drainage (PTGBD), endoscopic ultrasound-guided gallbladder drainage (EUS-GBD), or endoscopic transpapillary gallbladder drainage (ETGBD) are effective treatment options for gallbladder decompression. PTGBD is a well-established procedure and has been conventionally performed [2, 3], whereas EUS-GBD has been repeatedly confirmed as an effective treatment option that results in excellent technical and clinical success and good quality of life (QOL) because of its internal drainage feature. However, PTGBD and EUS-GBD may not be suitable for patients with ascites, coagulopathy, or anatomically inaccessible locations. Conversely, despite risk of developing endoscopic retrograde cholangiopancreatography (ERCP)-related adverse events (AEs) such as acute pancreatitis, and

lower technical success rates than those for PTGBD or EUS-GBD [4, 5, 6], ETGBD is beneficial to patients with ascites or coagulopathy and results in a high patient quality of life because of internal drainage [7, 8, 9, 10].

Two ETGBD methods have been established using either external (endoscopic naso-gallbladder drainage [ENGBD]) and internal (endoscopic gallbladder stenting [EGBS]) drainage. Previous randomized controlled trials have found no differences between ENGBD and EGBS in terms of technical success, clinical success, or early AEs rate [11, 12]. Therefore, although ENGBD enables drainage status monitoring, gallbladder lavage, and bile sampling, EGBS is considered superior in terms of patient QOL. While many previous reports about EGBS have described use of a 7F plastic stent [6, 11, 12, 13, 14, 15, 16], a few recent studies have reported treatment outcomes in EGBS using a 5F stent [17, 18]. Because of its small diameter, a 5F stent may offer good insertability; however, concerns remain about poor drainage or early stent occlusion. Nevertheless, no reports have compared outcomes with 7F and 5F stents and no evidence has been established about the appropriate stent diameter for EGBS.

Therefore, we designed a retrospective study that compared outcomes between 7F and 5F stents in patients undergoing EGBS for AC. The aim was to evaluate efficacy of a 5F plastic stent in EGBS. This was the first comparative study of outcomes between a 7F stent and a 5F stent in a relatively large number of EGBS cases.

Patients and methods

Patients

This retrospective, single-center study analyzed clinical data from 147 consecutive patients who underwent ETGBD for AC between January 2019 and July 2023 at St. Marianna University School of Medicine Hospital, a tertiary referral center in Japan. Inclusion criteria were as follows: 1) First time undergoing ETGBD for management of AC; 2) EGBS using a single pigtail plastic stent (GBest-N stent, Hanaco Medical Co., Saitama, Japan); and 3) undergoing a 3-day hospitalization observation postoperatively. Patients were excluded if they had any of the following: 1) prior history of upper gastrointestinal or biliary surgeries, except for gastrectomy with Billroth I reconstruction; 2) failed bile duct cannulation; 3) failed guidewire insertion into the gallbladder; or 4) underwent ENGBD or EGBS using stents other than a single pigtail plastic stent. The patients were divided into two groups: those who underwent EGBS using a 7F single pigtail stent between January 2019 and July 2021 (7F group) and those who underwent EGBS using a newly developed 5F single pigtail stent between August 2021 and July 2023 (5F group). The reason for excluding stents other than the single pigtail stent was to exclude bias due to differences in stent shape and material other than diameter.

All patients provided written informed consent prior to undergoing the endoscopic procedures. This study was approved by the Institutional Review Board of St. Marianna University School of Medicine (approval number: 6358).

Indications for ETGBD

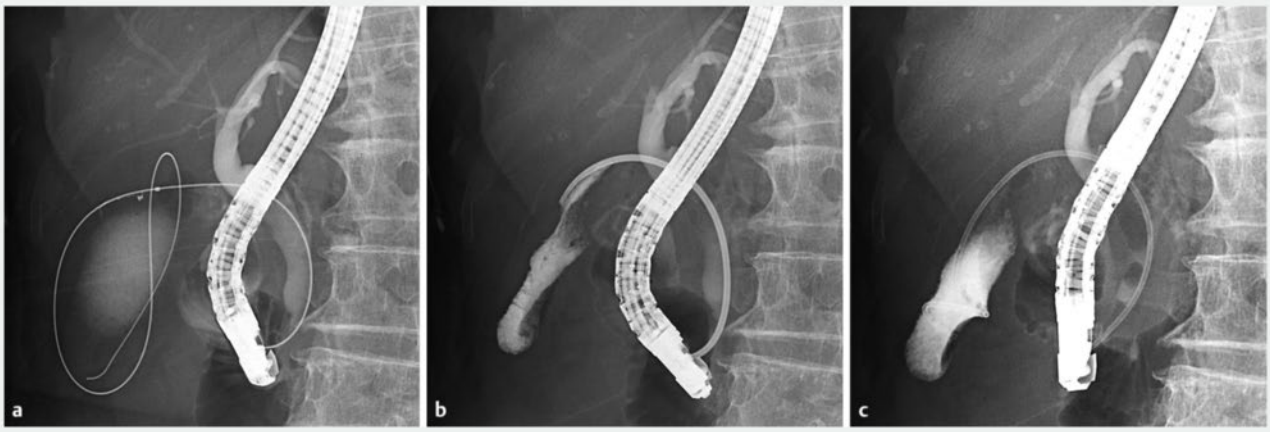
ETGBD was selected for patients who could not undergo urgent cholecystectomy or PTGBD because of coagulopathy, bleeding tendency, comorbidities, ascites, high risk of self-removal of the drainage catheter, or patient refusal of procedures. ETGBD was also selected for patients whose condition was complicated by bile duct stones or acute cholangitis.

EGBS procedure

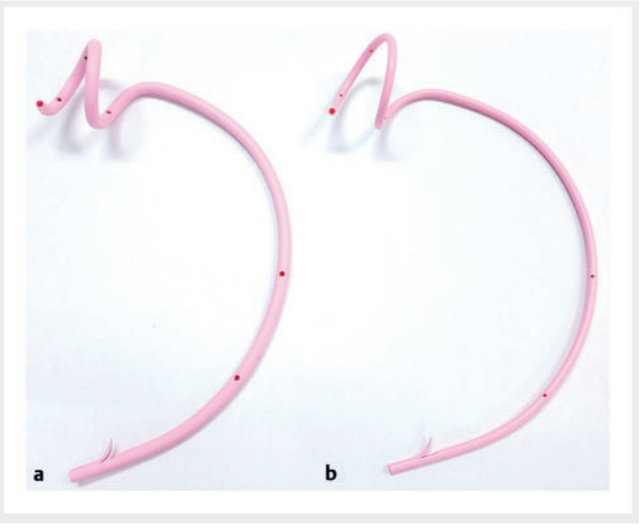
EGBS was performed using a duodenoscope in patients under moderate/deep sedation. After bile duct cannulation, cholangiography was performed to confirm the cystic duct. A 0.035- or 0.025-inch hydrophilic guidewire (Radifocus, Terumo, Tokyo, Japan, or NaviPro; Boston Scientific, Natick, Massachusetts, United States) was passed through the cystic duct and inserted into the gallbladder (▶ **Fig. 1a**). The bile was then suctioned, and the gallbladder was irrigated with saline through a cannula with a wide lumen (SHOREN, KANEKA Medix, Osaka, Japan) or a tapered catheter with side holes (MultiFunction Catheter, Gadelius Medical, Tokyo, Japan) (▶ **Fig. 1b**). After the guidewire was replaced with a 0.025-inch conventional type (VisiGlide2, Olympus, Tokyo, Japan), endoscopic sphincterotomy (EST) was performed if there was no bleeding tendency, such as antithrombotic drug intake or disseminated intravascular coagulation. Bile duct stones were removed if present, and a biliary stent was placed if complicated by biliary stricture. Finally, a single pigtail plastic stent (GBest-N stent, Hanaco Medical Co.) [15, 16] was placed to ensure that the stent tip was located at the fundus of the gallbladder (▶ **Fig. 1c**). A 7F diameter stent was used from January 2019 to July 2021 and a 5F diameter stent after August 2021. All ERCP procedures were performed under the supervision of an expert who had performed ≥ 1000 ERCP procedures. Ulinastatin was administered at a dose of 150,000 units on the day of the procedure to all patients to prevent post-ERCP pancreatitis. In general, we did not perform any scheduled stent exchanges after EGBS. Elective cholecystectomy after EGBS was performed in patients with indications for surgery.

Use of a single pigtail plastic stent

The single pigtail plastic stent (GBest-N stent; Hanaco Medical Co.) used was specifically developed for EGBS (▶ **Fig. 2**). The tip of the stent has a three-dimensional pigtail (spiral) shape, and the spiral has side holes inside it. The stent shaft is semicircular and also has side holes. The spiral-shaped tip and semicircular shaft were designed to prevent migration. The distal side of the stent is straight with a single flap. Stent lengths are available from 11 to 19 cm at 2-cm intervals. The stents are available in 7F and 5F diameters, both of which have the same shape and material. The 7F and 5F stents became commercially available in 2016 and 2021, respectively. We used a 7F diameter stent from January 2019 to July 2021 and a 5F diameter stent after August 2021.



▶ **Fig. 1** Endoscopic gallbladder stenting procedure. **a** Almoner hydrophilic guidewire was inserted into the gallbladder. **b** The bile was then suctioned, and the gallbladder was irrigated with saline through a tapered catheter with side holes. **c** A 5F single pigtail plastic stent was placed in the gallbladder.



▶ **Fig. 2** Single pigtail plastic stent (GBest-N stent; Hanaco Medical Co., Saitama, Japan) used in the study. **a** 7F. **b** 5F.

Measurements

We retrospectively analyzed data about the following: patient background; details of endoscopic procedures; clinical outcomes, including technical success of EGBS and clinical success for AC; procedure-related early AEs; and long-term AEs after EGBS. We subsequently compared these factors between the 7F and 5F groups.

The primary outcome of this study was to compare the technical success of EGBS and clinical success of AC between the groups. The secondary outcome was to compare procedure-related early AEs and long-term AEs between the groups.

Definitions

Diagnosis and severity of AC were determined according to the Tokyo Guidelines 2018 [19]. Technical success of EGBS was defined as successful stent placement in the gallbladder. Clinical success for AC was defined as improvement in clinical symptoms and laboratory data within 3 days after EGBS. Diagnosis and severity of early procedure-related AEs, including pancreatitis, bleeding, perforation, and cholangitis, were determined according to consensus guidelines by Cotton et al. [20]. Hyperamylasemia was defined as serum amylase levels that were normal before the procedure and increased to above the normal limit (> 132 IU/L) the next day without associated abdominal pain after EGBS. Late AEs were defined as problems such as recurrent cholecystitis, acute cholangitis, stent migration, and bile duct stones that developed 7 days after EGBS.

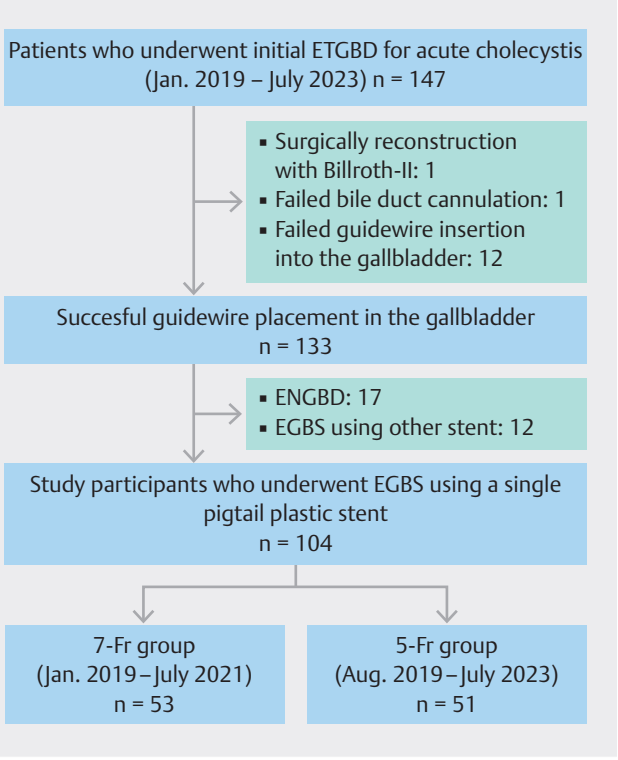
Statistical analysis

Categorical variables were compared using the chi-square and Fisher's exact tests. Continuous parameters were compared using Welch's *t*-test or the Mann-Whitney U test. Cumulative incidence of late AEs was estimated using Kaplan-Meier analysis and compared between the groups using the log-rank test. $P < 0.05$ was considered statistically significant. Statistical analysis was performed using StatMate IV software (ATMS Co. Ltd., Tokyo, Japan).

Results

Patient characteristics

Of the 147 patients who underwent ETGBD for AC during the study period, one with Billroth-II reconstruction, one with failed bile duct cannulation, and 12 with failed guidewire insertion into the gallbladder were excluded. Of the 133 patients with successful guidewire placement in the gallbladder, 17 who underwent ENGBD and 12 who underwent EGBS using another stent were excluded. In total, 104 patients fulfilled the eligibil-



▶ **Fig. 3** Flowchart of the patient selection process. ETGBD, endoscopic transpapillary gallbladder drainage; ENGBD, endoscopic nano-gallbladder drainage; EGBS, endoscopic transpapillary gallbladder stenting.

ity criteria and were included in the analysis. The 7F group included 53 patients, whereas the 5F group included 51 patients. A flowchart of the patient selection process is shown in ▶ **Fig. 3**.

Patient characteristics for the two groups are presented in ▶ **Table 1**. No difference in patient backgrounds before EGBS was observed between the two groups, except that the serum γ-GTP level was higher in the 5F group ($P = 0.01$).

Details of endoscopic procedures

A comparison of endoscopic procedures between the 7F and 5F groups is presented in ▶ **Table 2**. Analysis of endoscopic procedure-related variables revealed no significant differences between the two groups in performing EST, bile duct stone removal, bile duct stenting, pancreatography, prophylactic pancreatic stenting, or procedure time.

Clinical outcomes

Based on intention-to-treat analysis for the entire cohort of 147 patients, the technical success rate for ETGBD was 87.1% (128/147). A comparison of clinical outcomes between the 7F and 5F groups is presented in ▶ **Table 3**. No significant difference was found in the technical success rate for EGBS between the two groups (92.5% vs. 100%, $P = 0.14$). However, stent insertion was successful in all patients in the 5F group, whereas insertion failed in four patients in the 7F group because the stent tip became stuck in the cystic duct.

The clinical success rate for AC was 92.5% (49/53) in the 7F group and 98.0% (50/51) in the 5F group, with no significant difference ($P = 0.36$). In the technically successful EGBS cases, the clinical success rate was 100% in the 7F group and 98.0% in the 5F group. One patient in the 5F group in whom the procedure was clinically unsuccessful was in poor general condition because of severe cholecystitis with septic shock at presentation and died 3 days after EGBS

Procedure-related early AEs

A comparison of procedure-related early AEs between the two groups is presented in Table 3. The overall early AE rate for all subjects in both groups was 4.8% (5/104). Early AE rates in the 7F and 5F groups were 5.7% (pancreatitis: 3) and 3.9% (EST bleeding: 2), respectively, with no significant difference ($P = 0.96$). No case of pancreatitis was observed in the 5F group, whereas three patients in the 7F group developed mild pancreatitis. Incidence of hyperamylasemia was 24.5% in the 7F group and 9.8% in the 5F group, and the difference was significant ($P = 0.047$). Conservative therapy produced improvements in all patients with pancreatitis or hyperamylasemia.

Long-term AEs

A comparison of late AEs between the two groups in clinically successful cases after EGBS is presented in ▶ **Table 4**. Median follow-up periods in the 7F and 5F groups were 112 days (interquartile range [IQR] 59–658) and 129.5 days (IQR 26.25–288.5), respectively ($P = 0.50$). The late AE rate was 14.3% (recurrence of cholecystitis: 4; stent migration; 1; acute cholangitis: 1; and common bile duct stones: 1) in the 7F group and 10.0% (recurrence of cholecystitis: 2; stent migration: 3) in the 5F group, with no significant difference ($P = 0.73$). Median time to late AE was 238 days (IQR 125.5–508) for the 7F group and 187 days (IQR 23–295) for the 5F group, with no significant difference ($P = 0.33$). Furthermore, incidence of AEs at 3, 6, and 12 months after EGBS did not differ between the two groups. Kaplan-Meier analysis revealed no difference in cumulative incidence of late AEs [hazard ratio, 1.639; 95% confidence interval (CI), 0.526–5.157; log-rank $P = 0.39$] (▶ **Fig. 4**). The four patients with recurrent cholecystitis in the 7F group had a long time to recurrence of 139, 238, 358, and 933 days, respectively. Conversely, the two patients with recurrent cholecystitis in the 5F group had short-term recurrences of 12 and 23 days, but both developed short-term recurrence again for 28 and 17 days after replacement with the 7F stent.

Incidence of late AEs while waiting for elective cholecystectomy is shown in ▶ **Table 5**. Elective cholecystectomy was performed in 15 and 18 patients in the 7F and 5F groups, respectively ($P = 0.57$), and the median period from EGBS to cholecystectomy was 96 days (IQR 86.5–116.75) and 109 days (IQR: 90–135.5), respectively ($P = 0.41$). During the period leading up to surgery, no AEs were observed in the 7F group, whereas one case of recurrent cholecystitis was observed in the 5F group.

▶ **Table 1** Comparison of patient backgrounds between 7F and 5F groups.

	7F group (n = 53)	5F group (n = 51)	*P* value
Age (mean ± SD)	75.0 ± 15.0	76.2 ± 11.2	0.64
Sex (male/female)	33/20	30/21	0.72
Performance status (0–1/2–4)	31/22	29/22	0.87
Severity of acute cholecystitis			
▪ Mild	14	10	0.41
▪ Moderate	34	38	0.25
▪ Severe	5	3	0.76
Causes of acute cholecystitis			
▪ Gallstone	46	41	0.54
▪ Biliary metal stent	2	0	0.49
▪ Malignant biliary stricture	3	2	0.96
▪ Other	2	3	0.96
Laboratory data before EGBS (mean ± SD)			
▪ WBC (×103 μL)	11.9 ± 5.0	11.1 ± 4.5	0.39
▪ CRP (mg/dL)	12.6 ± 8.5	10.8 ± 8.1	0.27
▪ T-Bil (mg/dL)	1.8 ± 1.4	2.3 ± 1.8	0.12
▪ AST (U/l)	159.0 ± 480.1	159.7 ± 269.5	0.99
▪ ALT (U/l)	111.0 ± 212.4	150.7 ± 185.1	0.31
▪ γ-GTP (IU/l)	173.3 ± 180.6	289.3 ± 267.9	0.01
▪ AMY (U/l)	79.3 ± 99.7	118.4 ± 205.1	0.22
Previous EST	10	6	0.46
Periampullary diverticulum	19	15	0.48
Coexistence of pancreato-biliary diseases			
▪ Bile duct stone	17	19	0.58
▪ Pancreatic cancer	3	3	0.73
▪ Bile duct cancer	3	1	0.65
▪ Gallbladder cancer	1	0	0.98
▪ Other	2	1	0.97
Use of antithrombotic drug	24	17	0.21

SD, standard deviation; EGBS, endoscopic gallbladder stenting; EST, endoscopic sphincterotomy.

Discussion

EGBS is an effective alternative when cholecystectomy, PTGBD, or EUS-GBD are considered high risk [1, 9]. Many reports have demonstrated the efficacy of EGBS, most of which have traditionally used a 7F plastic stent [6, 11, 12, 13, 14, 15, 16]. In contrast, few reports of EGBS have described the use of a 5F stent. Two studies have recently reported the efficacy of EGBS with a 5F plastic stent [17, 18]. Doi et al. [17] performed EGBS in 40 patients with AC using a tailor-made 5F plastic stent fashioned by cutting a 5F ENBD catheter. The overall technical success rate was 75% (30/40) and the technical success rate in cases of successful guidewire placement in the gallbladder was 94% (30/32). Cholecystitis improved in 29 of 30 indwelling EGBS cases (97%) and the procedure-related early AE rate was 5.0%. Thirty-seven of 40 patients underwent elective cholecystectomy with a median waiting time of 42 (range: 12–138) days before surgery, and no AEs occurred during the waiting period. Takano et al. [18] also performed EGBS in 17 patients with AC using a 5F

▶ **Table 2** Comparison of endoscopic procedures between 7F and 5F groups.

	7F group (n = 53)	5F group (n = 51)	*P* value
EST	31	34	0.39
Bile duct stone removal	12	10	0.70
Bile duct stenting	7	3	0.35
Naso-biliary drainage	0	0	—
Accidental pancreatography	22	21	0.97
Prophylactic pancreatic stenting	8	9	0.93
Procedure time (mean ± SD, min)	46.4 ± 22.3	42.2 ± 17.0	0.28

EST, endoscopic sphincterotomy; SD, standard deviation

▶ **Table 3** Comparison of outcomes and early adverse events between 7F and 5F groups

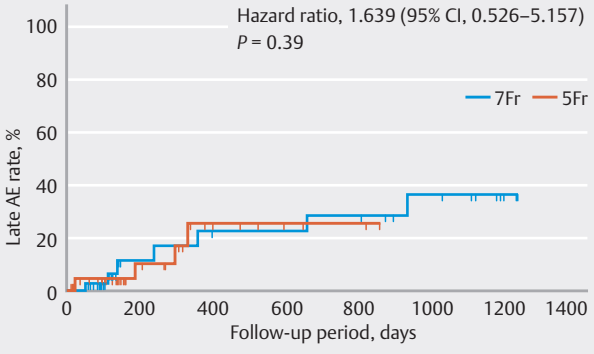
	7F group	5F group	*P* value
Outcomes			
▪ Technical success of EGBS (% (n))	92.5 (49/53)	100 (51/51)	0.14
▪ Clinical success for acute cholecystitis (% (n))	92.5 (49/53)	98.0 (50/51)	0.36
Early adverse events (% (n))	5.7 (3/53)	3.9 (2/51)	0.96
▪ Pancreatitis (n)	3	0	0.26
▪ Bleeding (n)	0	2	0.46
▪ Cholangitis (n)	0	0	—
Incidence of hyperamilasemia (% (n))	24.5 (13/53)	9.8 (5/51)	0.047
Serum amylase level a day after EGBS (mean ± SD, U/L)	214.6 ± 535.1	124.2 ± 138.0	0.24

EGBS, endoscopic gallbladder stenting; SD, standard deviation

▶ **Table 4** Comparison of long-term outcomes between 7F and 5F groups.

	7F group (n = 49)	5F group (n = 50)	*P* value
Follow-up periods (median (IQR), days)	112 (59–658)	129.5 (26.25–288.5)	0.50
Overall late adverse events (% (n))	14.3 (7)	10.0 (5)	0.73
▪ Recurrence of cholecystitis (n)	8.2 (4)	4.0 (2)	0.24
▪ Stent migration (n)	2.0 (1)	6.0 (3)	0.62
▪ Acute cholangitis (n)	2.0 (1)	0 (0)	0.99
▪ Common bile duct stones (n)	2.0 (1)	0 (0)	0.99
Time to late adverse events (median (IQR), days)	238 (125.5–508)	187 (23–295)	0.33
3-month adverse events (% (n))	2.0 (1)	4.0 (2)	0.99
6-month adverse events (% (n))	6.1 (3)	4.0 (2)	0.98
12-month adverse events (% (n))	10.2 (5)	10.0 (5)	0.76

IQR, interquartile range.



▶ **Fig. 4** Kaplan-Meier analysis of cumulative incidence of late adverse events.

plastic stent with a multilayered pigtail tip and a half-pigtail distal end (IYO stent, Gadelius Medical, Tokyo, Japan). A guidewire was successfully placed in all cases and the technical and clinical success rates were 91%. Only one case of post-EST bleeding was observed as a procedure-related early AE. Within the median observation period of 312 days (range: 109–742), late AEs including cholangitis (n = 1) and stent migration (n = 1) were observed, but no recurrence of cholecystitis was encountered. Thus, both previous studies that employed the 5F stent reported satisfactory results that were comparable to those using a 7F stent. However, because both reports were limited by the one-arm pilot study design with some patients, its superiority or inferiority to a 7F stent remains unclear. To date, no reports have compared outcomes between 5F and 7F stents in EGBS and our study is the first to do so in a relatively large number of EGBS cases. Moreover, to exclude bias due to differences in stent shape and material, we limited our analysis to patients who underwent EGBS using only the single pigtail plastic stent (GBest-N stent). Therefore, comparison of outcomes based on differences in stent diameter was likely to be highly reliable.

▶ **Table 5** Comparison of preoperative outcomes in patients undergoing cholecystectomy between 7F and 5F groups.

	7F group (n = 49)	5F group (n = 50)	*P* value
Elective cholecystectomy after EGBS (n)	15	18	0.57
Time to cholecystectomy (median (IQR), days)	96 (86.5–116.75)	109 (90–135.5)	0.41
Adverse events before cholecystectomy (% (n))	0 (0/15)	5.6 (1/18)	0.93
▪ Recurrence of cholecystitis	0	1	0.93
▪ Stent migration	0	0	—
▪ Acute cholangitis	0	0	—

IQR, interquartile range.

ETGBD is technically challenging and recent meta-analyses have reported pooled technical success rates of 83% to 86%, which is lower than that for PTGBD or EUS-GBD [21, 22, 23, 24]. Technical difficulty with ETGBD is associated with inherent complexity of inserting the guidewire into the gallbladder. Moreover, even when guidewire placement in the gallbladder is successful, subsequent stent insertion may be complicated. The stent may become stuck in the cystic duct because of impacted stones, a gap between the guidewire and stent tip, and tight tortuousness, resulting in stent insertion failure. Theoretically, a smaller-caliber stent has better insertability because it can easily pass through the narrow cystic duct and because the gap between the guidewire and the stent tip is small. In this study, the success rate for stent insertion after successful guidewire placement did not differ significantly between the 7F and 5F stents (7F group 92.5%; 5F group 100%; $P = 0.14$). However, stent insertion was successful in all patients in the 5F group, whereas stent insertion failed in four patients in the 7F group because the stent tip got stuck in the cystic duct. Therefore, although our results showed no statistically significant difference, the 5F stent may have better insertability. If guidewire or cannula insertion into the gallbladder is difficult, a 5F stent may be selected for successful subsequent stent insertion.

Recent meta-analyses have revealed that the pooled clinical success rate for ETGBD ranged from 79% to 93%, which is inferior to that for EUS-GBD [21, 22, 23, 24]. These meta-analyses included reports about EUS-GBD using a lumen-apposing metal stent and the excellent drainage through the large-bore lumen-apposing metal stent may have contributed to good clinical success. Conversely, the small-caliber plastic stent used in EGBS, especially the 5F, raises concerns about insufficient drainage due to debris and viscous bile. However, no difference in clinical success was found between the 7F and 5F groups in this study. Furthermore, clinical success rates for the 7F and 5F groups were 100% and 98%, respectively, which are both extremely favorable. Suctioning viscous bile and irrigation of the gallbladder with saline through a wide-lumen cannula before stent placement may have contributed to this favorable outcome. Therefore, by suctioning bile and gallbladder irrigation before stenting, EGBS using a 5F stent can achieve clinical success comparable to that for a 7F stent.

The overall ERCP procedure-related early AE rate in our study was 4.8%, which is comparable to those from previous reports [21, 22, 23], with no significant difference observed between the 7F and 5F groups. Therefore, the two stent diameters are both comparably safe and acceptable. However, the 5F group had a significantly lower incidence of hyperamylasemia ($P = 0.047$) and none of the patients developed pancreatitis. Although stent placement across the papilla may obstruct the outflow of pancreatic juice, a 5F stent may cause less interference. In subjects undergoing EGBS, EST often cannot be performed because of coagulopathy or anticoagulant medication use. Thus, a 5F stent may be preferable in such cases.

In this study, no significant difference was found in incidence of late AEs between the 7F and 5F groups, and the median time to late AEs was relatively long in both groups (238 days and 187 days in the 7F and 5F groups, respectively, $P = 0.33$). The rate of recurrence of cholecystitis also did not differ between the two groups: 8.2% in the 7F group and 4.0% in the 5F group ($P = 0.24$), which were comparable to the pooled recurrence rate of cholecystitis of 4.6% (95% CI 2.8–7.4) reported in a recent meta-analysis [22]. Theoretically, large-diameter stents would have longer patency because the inner cavity would take longer to fill with foreign substances. Median patency of a plastic stent placed in the common bile duct for biliary stricture is 4 to 5 months, even with a large diameter of 10F, and occlusion risk increases rapidly after 3 months [25, 26]. Therefore, most guidelines recommend that biliary stents be removed or changed every 3 months on a scheduled basis [27]. However, clear recommendations regarding long-term management of gallbladder stents have not been established. Although reports about long-term outcomes of EGBS are few, better long-term outcomes than those for biliary stenting have been reported [13, 16, 18, 28]. These excellent long-term outcomes may be the result of the "wicking" phenomenon, which maintains continuous drainage beside the stent even if the stent is occluded [29, 30]; thus, stent patency may not be the only essential factor for maintaining bile flow. In addition, the stent itself prevents stone impaction within the cystic duct or neck of the gallbladder, thereby reducing risk of cholecystitis recurrence and making long-term stent placement possible. Therefore, regardless of stent caliber, even a smaller 5F stent is acceptable, not only for EGBS before scheduled cholecystectomy, but also for permanent EGBS.

This study has several limitations. The study period differed between the 7F and 5F groups and the patients in the 5F group were more recent cases than those in the 7F group. Therefore, technical skill of endoscopists may have influenced the results. Most of the previous reports about EGBS used double pigtail stents, which were developed as stents for the bile duct, whereas in this study, a stent with a spiral tip and semicircular shaft was used, which was specifically developed for the gallbladder. Therefore, results from this study may differ slightly

from those in previous reports. In particular, the stent used in this study may have had less migration than a traditional pigtail stent because of its purposely designed shape. Moreover, this study used a retrospective design; therefore, a prospective randomized controlled trial is warranted to confirm our findings.

Conclusions

In conclusion, in EGBS for AC, a 5F stent can provide comparable outcomes to those for a 7F stent and help prevent hyperamylasemia. Although additional validation in a larger number of cases is required, use of a 5F stent may contribute to improved technical success and prevention of post-EGBS pancreatitis.

Acknowledgement

This study was partially supported by a grant from JSPS KAKENHI (Grant Number 23K07405)

Conflict of Interest

The authors declare that they have no conflict of interest.

Funding Information

JSPS KAKENHI 23K07405

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