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Article type　　: Original article

Performance of a new short-type double-balloon endoscope with advanced force transmission and adaptive bending for pancreaticobiliary intervention in patients with surgically altered anatomy: A propensity-matched analysis

Running title: Performance of a new short-type DBE

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Author Contributions: Yamada A and Kogure H designed the study and were the main authors of the manuscript; Nakai Y, Takahara N, Mizuno S, Tada M, and Koike K revised the article for important intellectual content. All authors read and approved the submitted version of the manuscript.

Abstract

Background and Aims: A new short-type double-balloon endoscope (DBE) has been developed with a major focus on facilitating scope insertion to the target site for pancreaticobiliary interventions in patients with surgically altered anatomy. We investigated the performance of this new short-type DBE by comparing it with a conventional DBE.

Methods: Data from 885 endoscopic retrograde cholangiopancreatography (ERCP) procedures using balloon endoscopy were analyzed. We used propensity score matching to adjust for differences between patients who underwent ERCP procedures using the new short-type DBE versus the conventional short-type DBE.

Results: A total of 163 pairs of patients were selected via propensity score matching. The success rate of reaching the target site was 100% in both the new DBE group and the conventional DBE group (P = 1.0). The new DBE group had a shorter insertion time required to reach the target site than the conventional DBE group (10 min vs. 14 min, P < 0.01). The success rate of the pancreaticobiliary interventions in the new DBE group was as high as that in the conventional DBE group (92% vs. 89% P = 0.35). The overall procedure time decreased from 62 min in the conventional DBE group to 55 min in the new DBE group (P =

0.26). No significant differences in the rates of adverse events were observed between the two groups.

Conclusions

A new short-type DBE allows faster insertion to the target site for pancreaticobiliary intervention in patients with surgically altered anatomy.

Keywords: Double-balloon endoscope, endoscopic retrograde cholangiopancreatography, patients with surgically altered anatomy

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) for patients with surgically altered gastrointestinal anatomy remains challenging. Recently, short-type double-balloon endoscopes (DBEs) for pancreaticobiliary interventions in patients with surgically altered anatomy have become available in many institutions[1-15]. The success rates, of reaching the target site and of ERCP-related interventions associated with use of these endoscopes, are reported to range between 73–100% and 85–100%, respectively[15, 16]. However, we previously demonstrated in a multicenter study that ERCP using a conventional short-type DBE (EI-530B; Fujifilm, Tokyo, Japan) is a lengthy procedure, requiring approximately 22 ± 20 minutes to reach the target site and 56 ± 33 minutes to complete ERCP-related interventions[16]. Improved ease of insertion of the endoscope to the target site can allow for safe and

minimally invasive pancreaticobiliary interventions in patients with surgically altered anatomy.

Recently, a new short-type DBE (EI-580BT; Fujifilm) was developed with a focus on facilitating scope insertion to the target site for pancreaticobiliary interventions (Table 1). The EI-580BT endoscope is equipped with an advanced force-transmission insertion tube[17] and adaptive bending[17] that can pass through the angulated afferent loop easily. Moreover, the tip has a smaller bending radius and a 3.2-mm working channel, which enables an easier approach to the papilla and a smooth switching of ERCP devices. It also allows application of the double-guidewire technique, wire-guided mechanical lithotripters, and covered metal stents with a 9 Fr delivery system.

To compare the performance of the new DBE (EI-580 BT) with that of a conventional one (EI-530B), the different endoscope groups were matched according to baseline characteristics. A propensity-matched analysis was conducted to compare performance between the EI-580BT and EI-530B endoscopes using the ERCP database of the University of Tokyo.

Methods

Study design, setting, and participants

The prospectively collected ERCP database of the University of Tokyo was used in this study. Each endoscopist inputted patient data and endoscopic findings into the database immediately after each ERCP procedure. The database included the following information: patient

characteristics (age, sex, diagnosis, and history of gastrointestinal tract surgery), procedure data (type of endoscope, success of reaching the target site, insertion time, cannulation success, interventions performed after cannulation, and overall procedure time), procedure outcome data, and ERCP-related adverse events[18]. We systematically selected data from 885 cases with surgically altered anatomy that underwent ERCP using balloon endoscopy between December 2005 and February 2017. To reduce the influence of systematic bias, such as the learning curve, we excluded 325 cases using a conventional short-type DBE (EC-450BI5) performed during the introduction period. Additionally, 15 cases using a long type DBE (EN-450T5), and 56 cases using a single-balloon endoscope (Olympus, Tokyo, Japan) were also excluded. Therefore, a total of 489 ERCP procedures using the EI-580BT or EI-530B endoscope were considered eligible for inclusion (Fig 1). This study complied with the Declaration of Helsinki and was approved by the Research Ethics Committee of The University of Tokyo.

ERCP using a short-type double-balloon endoscope

Each procedure using a short type DBE was performed by two expert endoscopists (AY and HK) who had performed at least 300 ERCP procedures using a conventional short-type DBE EC450-BI5 before the present study (Fig. 1). All procedures were performed under conscious sedation administered by the endoscopists. CO_2 insufflation was used during the procedure to reduce intraluminal gas. A short-type DBE was inserted into the afferent loop in a selective and retrograde fashion until it reached the target site (i.e., the major papilla,

hepaticojejunostomy anastomosis, or pancreaticojejunostomy anastomosis). After the scope reached the target site, biliary or pancreatic duct cannulation was attempted using an ERCP catheter. After diagnosis via cholangiography or pancreatography, endoscopic biliary interventions or endoscopic pancreatic interventions, such as endoscopic papillary balloon dilation, balloon dilation of the anastomosis, stone extraction, and stent placement, were performed.

Variables and outcomes

Patient characteristics including age, sex, surgical anatomy, pancreaticobiliary intervention indications, ERCP findings, and adverse events were evaluated. The definition of altered surgical anatomy included gastrectomy with Billroth II (B-II), gastrectomy with Roux-en-Y (R-Y), pancreaticoduodenectomy (PD) with B-II, PD with R-Y, hepaticojejunostomy with R-Y, and liver transplantation with hepaticojejunostomy. The indications for pancreaticobiliary intervention included biliary strictures, anastomosis stenoses, choledocholithiasis, intrahepatic stones, obstructive jaundice, bile duct leaks, pancreatic duct leaks, and chronic pancreatitis with pancreatic duct strictures and intraductal pancreatic stones. The outcomes of interest were as follows: the success rate of reaching the target site, the success rate of the pancreaticobiliary intervention, the insertion time required to reach the target site, the overall procedure time, the success rate of cannulation of the papilla of Vater, the time to cannulation of the papilla of Vater, and adverse events during or after the ERCP procedure. The success rate of cannulation of the papilla of Vater and the time to

its cannulation were calculated for patients who did not receive hepaticojejunostomy or pancreaticojejunostomy. The following conditions were defined as ERCP-related adverse events: pancreatitis (abdominal pain with hyperamylasemia requiring at least 2 days of unplanned hospitalization after the procedure[19]), perforation, and bleeding (hematemesis and/or melena or a hemoglobin drop > 2 g/dL). We also assessed recurrent pancreaticobiliary events after successful pancreaticobiliary interventions. Recurrent pancreaticobiliary events included biliary strictures, anastomosis stenosis, choledocholithiasis, intrahepatic stones, obstructive jaundice, bile duct leaks, pancreatic duct leaks, and chronic pancreatitis with pancreatic duct strictures and intraductal pancreatic stones that required pancreaticobiliary intervention. Scheduled stent replacements were not included in recurrent pancreaticobiliary events.

Statistical analysis

For ERCP procedures using an EI-580BT endoscope, the propensity score was estimated using a logistic regression model as a function of patient demographic data, including age, sex, and surgical anatomy, which were considered potentially clinically significant variables. We performed a one-to-one matching analysis between the EI-580BT group and the EI-530B group using the nearest neighbor method, within a caliper of width of 0.2 of the standard deviation of the logit of the propensity score (Fig 1). After propensity matching, the differences in the success rate of reaching the target site, the success rate of the pancreaticobiliary intervention, the insertion time required to reach the target site, the overall

procedure time, the success rate of cannulation of the papilla of Vater, the time to cannulation of the papilla of Vater, and adverse events during or after the procedure were compared between the two groups using Fisher's exact test, the Chi-square test, or the Kruskal-Wallis test as appropriate. Three subgroup analyses of patients with R-Y reconstruction with gastrectomy, patients with R-Y reconstruction with PD and patients with R-Y reconstruction with hepaticojejunostomy were also performed. The endpoint of the recurrence analysis was pancreaticobiliary events after successful pancreaticobiliary interventions that required pancreaticobiliary intervention, and data were censored on the date of the final visit. The number of recurrences between the EI-580BT and EI-530B groups was evaluated using the log-rank test in univariate analyses. A P-value < 0.05 was considered to indicate statistical significance. All statistical analyses were conducted using STATA® software (ver. 13.0; Stata Corporation, College Station, TX, USA) and JMP® Pro software (ver. 13.0; SAS Institute Inc., Cary, NC, USA).

Results

Patient selection

The demographic and clinical characteristics of all patients (n = 489) and propensity score-matched patients (n = 326) are shown in Table 2. Some differences were found between the groups before propensity score matching. The group subjected to EI-580BT endoscopy had a higher proportion of older and female patients. Moreover, there was a significant difference in surgical anatomy between the EI-580BT and EI-530B groups. The

area under the receiver operating characteristic curve for propensity scores for the EI-580BT group was 0.721. After one-to-one propensity score matching, 163 pairs in the EI-580BT and EI-530B groups were selected, and both groups had similar characteristics.

Endoscopic procedure results and adverse events

The endoscopic procedure results of each propensity-matched patient group are shown in Table 3. Using a short type DBE, reaching the target site was achieved in all cases of both the EI-580BT and EI-530B groups. The insertion time required to reach the target site was significantly shorter in the EI-580BT group than in the EI-530B group. The success rate of the pancreaticobiliary interventions in the EI-580BT group was as high as that in the EI-530B group. The median overall procedure time decreased from 62 min in the EI-530B group to 55 min in the EI-580BT group, although this difference was not statistically significant. Apart from hepaticojejunostomy and pancreaticojejunostomy cases, the success rate of cannulation of the papilla of Vater in the EI-580BT group was higher than that in the EI-530B group, although this difference was not statistically significant.

Subgroup analyses of the endoscopic procedure results in patients with R-Y reconstruction with gastrectomy, patients with R-Y reconstruction with PD and patients with R-Y reconstruction with hepaticojejunostomy are shown in Table 4. Among the patients with R-Y reconstruction with hepaticojejunostomy, the EI-580BT endoscope had a significantly shorter insertion time to the target site than the conventional endoscope. However, a difference in insertion time to the target site was not observed between the two groups among patients with

R-Y reconstruction with gastrectomy and patients with R-Y reconstruction with PD. In patients with R-Y reconstruction with gastrectomy, the success rates of cannulation of the papilla of Vater and of the pancreaticobiliary intervention using the EI-580BT endoscope were higher than that using a conventional endoscope.

Adverse events between the groups are shown in Table 5. Pancreatitis occurred in six patients in the EI-580BT group and five patients in the EI-530B group. Perforations occurred in one patient in the EI-580BT group and six patients in the EI-530B group. No major perforations detected by enteroscopy occurred. Fluoroscopy and CT showed retroperitoneum emphysema in all patients and the locations of all perforations were estimated to be the afferent loop. All patients recovered with conservative treatment.

Recurrence after successful pancreaticobiliary intervention

Of the 150 successful procedures in the EI-580BT group, 20 (13.3%) pancreaticobiliary events occurred during a mean follow-up period of 16.5 months. Of the 145 successful procedures in the EI-530B group, 26 (17.9%) pancreaticobiliary events occurred during a mean follow-up period of 26.4 months. There were no statistically significant differences between the groups (log-rank test $P = 0.51$).

Discussion

We evaluated the performance of the new short-type DBE EI-580BT for pancreaticobiliary interventions in patients with surgically altered anatomy, and found that the EI-580BT endoscope had a significantly shorter insertion time to the target site than the conventional endoscope. Furthermore, the success rate of cannulation of the papilla of Vater and the success rate of pancreaticobiliary intervention using the EI-580BT endoscope were significantly higher than that using a conventional endoscope in patients with R-Y reconstruction with gastrectomy.

Balloon endoscopy enables deep insertion of an endoscope without a redundant loop, allowing for pancreaticobiliary interventions in patients with surgically altered anatomy, such as for R-Y and B-II reconstruction. Moreover, the EI-580BT endoscope includes two new features: an advanced force-transmission insertion tube and adaptive bending[16]. The advanced force-transmission insertion tube improves the force-transmission of the rotating force by modifying the exterior surface of the endoscope. Adaptive bending allows for stiffness gradation of the flexible portion of the endoscope, which enables it to pass the angulation without sticking. Shimatani et al. reported the utility and safety of the EI-580BT endoscope; however, that study did not include a control group.[20] Therefore, compared to the conventional short-type DBE, it remains unknown whether the new features of the EI-580BT endoscope improve scope insertion, pancreaticobiliary intervention, and safety. In the present study, the two new features of the EI-580BT endoscope appeared to have produced a substantial improvement with respect to insertion of the endoscope into the afferent loop

through the sharp angulation in procedures such as jejuno-jejunostomy, resulting in a significantly shorter insertion time to the target site. Specifically, the EI 580-BT scope was advantageous in patients with R-Y reconstruction with hepaticojejunostomy, which had a longer length to the target site than patients with R-Y reconstruction with gastrectomy and PD. Although the difference appeared to be only 4 min, which is a fraction of the total procedure time, the insertion time of the EI-580BT endoscope decreased by about 30%. We believe that improved scope insertion can allow for a safer and more minimally invasive pancreaticobiliary intervention in patients with surgically altered anatomy.

The EI-580BT endoscope has a larger working channel, measuring 3.2 mm in diameter, compared to the conventional short-type DBE working channel, which measures 2.8 mm. Additionally, the tip of the EI-580BT has a smaller bending radius. These features allow for an easier approach to the papilla and smoother accessory insertion[21]. In fact, in the present study, the success rate of cannulation of the papilla using the EI-580BT endoscope was higher than that using the EI-530B endoscope, especially in patients with R-Y reconstruction with gastrectomy. Furthermore, the double-guidewire technique, wire-guided mechanical lithotripters, and covered metal stents with a 9 Fr delivery system can also be used with this endoscope. These features of the EI-580BT endoscope may make it possible to perform pancreaticobiliary interventions for otherwise difficult cases using a conventional short-type DBE[22].

The most serious adverse event associated with ERCP using balloon endoscopy in patients with surgically altered anatomy is perforation. Interestingly, the EI-580BT endoscope tended to decrease the prevalence of perforation, although the number of adverse events was small and not statistically significant. A possible explanation for this may be the effect of stiffness gradation of the flexible portion, which enables the endoscope to pass the angulation without sticking.

This study had several strengths. First, we assessed a large number of patients. Next, we included more than 300 cases of ERCP experience using a conventional short-type DBE EC450-BI5 before the present study. Therefore, there was only a limited influence of systematic bias on our results.

However, our study was not without limitations. First, it was a retrospective analysis. Although we used a propensity-matched analysis to reduce the effects of observed group differences on causal estimates, our study was still subject to biases due to unobserved differences including the length to the target site. Second, unmeasurable confounders associated with the procedures, including underlying diseases, may have been present. Third, propensity-matched analyses result in the loss of eligible subjects due to the lack of matched pairs, reducing the overall sample size and negatively affecting statistical power.

In conclusion, the EI-580BT endoscope, a new short-type DBE that features an advanced force transmission insertion tube and adaptive bending, allows faster insertion to the target site than a conventional endoscope. In patients with R-Y reconstruction with gastrectomy, the success rate of cannulation of the papilla of Vater and the success rate of the pancreaticobiliary intervention using the EI-580BT endoscope were significantly higher than that using a conventional endoscope.

Acknowledgments

The EI-580BT endoscope was provided by Fujifilm Medical Co., Ltd. for collaborative research. This agency had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript. No author has any conflict of interest to disclose.

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Table 1. Features of the newer version of the short-type DBE (EI-580BT) and conventional DBE (EI-530B)

	EI-580BT	EI-530B
Working length	1550 mm	1520 mm
Total length	1850 mm	1820 mm
Distal end diameter	9.4 mm	9.4 mm
Flexible portion diameter	9.3 mm	9.3 mm
Diameter of the working channel	3.2 mm	2.8 mm
Clock position of instrument entry	5:30	6:30
Advanced force transmission function	Yes	No
Adaptive bending system	Yes	No

Table 2. Demographic and clinical characteristics of the EI-580BT and EI-530B groups

Characteristics	All patients			Propensity-matched patients		
	EI-580BT (n = 214)	EI-530B (n = 275)	P-value	EI-580BT (n = 163)	EI-530B (n = 163)	P-value
Age, year	64.1 ± 15.5	62.8 ± 16.8	0.39*	64.9 ± 15.5	65.4 ± 15.8	0.74*
Sex (male)	111 (52%)	186 (68%)	< 0.01**	93 (57%)	91 (56%)	0.82**
Surgical anatomy			< 0.01**			0.89**
Gastrectomy with B-II	18 (8%)	17 (6%)		16 (10%)	13 (8%)	
Gastrectomy with R-Y	45 (21%)	64 (23%)		36 (22%)	46 (28%)	
PD with B-II	38 (18%)	30 (11%)		29 (18%)	24 (15%)	
PD with R-Y	22 (10%)	65 (24%)		22 (14%)	20 (12%)	
Hepaticojejunostomy with R-Y	77 (36%)	73 (27%)		49 (30%)	47 (29%)	
Liver transplantation with hepaticojejunostomy	12 (6%)	24 (9%)		9 (6%)	11 (7%)	
Prior ERCP experience using balloon endoscope	155 (72%)	186 (68%)	0.22**	121 (74%)	110 (67%)	0.15**
Indications†			0.13**			0.70**
Biliary strictures	52 (24%)	72 (26%)		37 (23%)	35 (21%)	
Anastomosis stenoses‡	82 (38%)	89 (32%)		60 (37%)	53 (33%)	
Choledocholithiasis	56 (26%)	64 (23%)		47 (29%)	47 (29%)	
Intrahepatic stone	31 (14%)	57 (21%)		24 (15%)	31 (19%)	
Miscellaneous§	4 (0.5%)	13 (5%)		4 (2.5%)	7 (4.2%)	

Data are expressed as means ± standard deviations or *n* (%). *Unpaired Student's *t*-test.

**Chi-square test.

†Duplicated data allowed.

‡Hepaticojejunostomy or pancreaticojejunostomy.

§Miscellaneous indications included obstructive jaundice, bile duct leaks, pancreatic duct leaks, and chronic pancreatitis with pancreatic duct strictures and intraductal pancreatic stones.

Abbreviations: B-II, Billroth II; PD, pancreaticoduodenectomy; R-Y, Roux-en-Y; ERCP, endoscopic retrograde cholangiopancreatography

Table 3. Endoscopic procedure results in propensity-matched patients

	Propensity-matched patients		
	EI-580BT (n = 163)	EI-530B (n = 163)	P-value
Successfully reached the target site	163 (100%)	163 (100%)	1.0**
Insertion time, min	10 (6–20)	14 (8–26)	< 0.01*
Overall procedure time, min	55 (37–87)	62 (41–88)	0.26*
Successful cannulation of the papilla of Vater†	96%	87%	0.10*
Time to cannulation of the papilla of Vater†, min	3 (1–20)	5.5 (2–16)	0.70*
Successful pancreaticobiliary interventions	150 (92%)	145 (89%)	0.35**
Pancreaticobiliary intervention‡			0.59**
Biliary stone extraction	71 (44%)	77 (47%)	
Biliary plastic stenting	52 (32%)	49 (30%)	
Biliary metallic stenting	14 (9%)	6 (4%)	
Balloon dilation of biliary anastomotic stricture	50 (31%)	56 (34%)	
Endoscopic papillary balloon dilation	29 (18%)	30 (18%)	
Endoscopic papillary large balloon dilation	15 (9%)	9 (6%)	
Endoscopic naso-biliary drainage	75 (46%)	76 (47%)	
Pancreatic stone extraction	3 (2%)	6 (4%)	
Pancreatic plastic stenting	5 (3%)	8 (5%)	
Balloon dilation of pancreatic anastomotic stricture	5 (3%)	9 (6%)	
Endoscopic naso-pancreatic drainage	7 (4%)	9 (6%)	

Data are expressed as medians (*interquartile range*) or *n* (%); *Kruskal-Wallis test.

**Chi-square test.

†Cases after hepaticojejunostomy or pancreaticojejunostomy were excluded. ‡Duplicated data allowed.

Table 4. Subgroup analyses of endoscopic procedure results in patients with R-Y reconstruction

	Propensity-matched patients		
	EI-580BT	EI-530B	P-value
Patients with R-Y reconstruction with gastrectomy	n = 36	n = 46	
Successfully reached the target site	36 (100%)	46 (100%)	1.0**
Insertion time, min	11.5 (8–22)	13 (8–21)	0.68*
Overall procedure time, min	68 (47–88)	68 (45–95)	1.0*
Successful cannulation of the papilla of Vater	36 (100%)	38 (83%)	< 0.01**
Time to cannulation of the papilla of Vater, min	5 (1–20)	5.5 (1–17)	0.85*
Successful pancreaticobiliary interventions	36 (100%)	36 (78%)	< 0.01**
Patients with R-Y reconstruction with PD	n = 22	n = 20	
Successfully reached the target site	22 (100%)	20 (100%)	1.0**
Insertion time, min	10 (3–23)	13.5 (7–22)	0.30*
Overall procedure time, min	57 (34–92)	51.5 (37–80)	0.60*
Successfully reached the target site	22 (100%)	20 (100%)	1.0**
Patients with R-Y reconstruction with hepaticojejunostomy	n = 49	n = 47	
Successfully reached the target site	49 (100%)	47 (100%)	1.0**
Insertion time, min	13 (8–25)	23 (13–37)	<0.01*
Overall procedure time, min	61 (43–84)	74 (49–100)	0.24*
Successful pancreaticobiliary interventions	48 (98%)	43 (91%)	0.15**

Data are expressed as medians (*interquartile range*) or *n* (%); *Kruskal-Wallis test.

**Chi-square test.

Abbreviations: R-Y, Roux-en-Y; PD, pancreaticoduodenectomy

Table 5. Adverse events in propensity-matched patients

	Propensity-matched patients		
	EI-580BT (n = 163)	EI-530B (n = 163)	P-value
Pancreatitis	6 (4%)	5 (3%)	0.75*
Perforation	1 (1%)	6 (4%)	0.12*
Bleeding	0 (0%)	0 (0%)	N/A

Data are expressed as *n* (%). * Fisher's exact test. Duplicated data allowed.

Abbreviations: N/A, not applicable.

Figure legends

Figure 1. Study flow chart.

Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography.