EI-580BT in Clinical Studies

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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

Introduction: The study by A. Yamada et. al. titled "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"[1] compared performance between the conventional EI-530B scope, comparable to the EC-450BI5 scope available in the US, and the new short-type double balloon EI-580BT scope in a propensity-matched analysis. It was described that the new short-style scope was developed with a major focus on facilitating scope insertion in patients with surgically altered anatomy. This study shows the benefits of these features in this first-of-its-kind double balloon scope in the US.

Study Design: The study was a retrospective review of data entered into an ERCP database following ERCP procedures performed at the University of Tokyo. A total of 489 ERCP procedures were considered eligible for inclusion in the study and a total of 163 propensity-matched cases for both the EI-530B and EI-580BT were examined. Differences in the success rates of reaching the target site, pancreaticobiliary intervention, and cannulation of Vater's papilla as well as insertion time required to reach the target site, time to cannulation of Vater's papilla, overall procedure time, and adverse effects of each group were compared.

Results: In both groups, reaching the target site was achieved in all cases. Insertion time required to reach the target site was significantly shorter in the EI-580BT group than in the EI-530B group, with a median of 10 minutes in the EI-580BT group and 14 minutes in the EI-530B group. The success rate of pancreaticobiliary interventions was high in both groups, with 92% in EI-580BT and 89% in EI-530B. The success rate of cannulation of Vater's papilla is 96% in the EI-580BT group and 87% in the EI-530B group. The median overall procedure time and time to cannulation of Vater's papilla, though not statistically significant, was 7 minutes less and two minutes less in the EI-580BT group respectively. Lastly, there were no significant differences in adverse effects in the two groups, however, adverse effects included pancreatitis in 6 patients of the EI-580BT group and 5 patients in the EI-530B group. Perforation occurred in one patient in the EI-580BT group and in 6 patients in the EI-530B group.

Examining the subgroup analysis of patients with Roux-en-Y (R-Y) reconstruction with gastrectomy, R-Y reconstruction with pancreaticoduodenectomy, and R-Y reconstruction with hepaticojejunostomy, there were significant differences between the two groups. The R-Y reconstruction with gastrectomy patients

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Endoscopic procedure results in 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 Vater's papilla, %	96	87	0.10*
Time to cannulation of Vater's papilla, min	3 (1-20)	5.5 (2-16)	0.70*
Successful pancreaticobiliary interventions	150 (92%)	145 (89%)	0.35**

Table 1. Endoscopic procedure results in propensity-matched patients see Table 3 in original publication. *Kruskal-Wallis test. **Chi-squared test.

showed significantly higher success rates in the cannulation of Vater's papilla and pancreaticobiliary intervention with 100% success rates using the EI-580BT scope. Furthermore, there was significantly shorter insertion time in patients with R-Y reconstruction with hepaticojejunostomy, with a median of 13 minutes for the EI-580BT and 23 minutes for EI-530B.

Discussion: The EI-580BT endoscope features advanced force transmission, adaptive bending, a larger working channel and smaller bending radius, allowing for faster insertion to the target site than with a conventional endoscope. The new short-type DBE allows faster insertion to the target site for pancreaticobiliary intervention in patients with surgically altered anatomy. The EI-580BT's larger working channel (3.2 mm) accommodates devices and provides greater suction capability, and the smaller bending radius, allowing for an easier approach to the papilla and smoother accessory insertion.[2]

The advanced force transmission improves the force transmission of the rotating force by modifying the exterior surface of the EI-580BT. The adaptive bending allows for stiffness gradation of the flexible portion, which enables it to pass the angulation without sticking. Additionally, this may be a possible explanation in regards to the adverse effects, specifically perforation. These two new features have shown to be an improvement in insertion and therefore significantly shorter time to the target site. In patients with R-Y reconstruction with hepaticojejunostomy, insertion time with the EI-580BT decreased about 30%.[1] The success rate of cannulation of Vater's papilla and pancreaticobiliary in patients with R-Y reconstruction with gastronomy were significantly higher than a conventional endoscope. In conclusion, the short-type DBE has features that allow for benefits of time-saving and possibly safer interventions in patients with surgically altered anatomy.

Why it's relevant: This publication illustrates Fujifilm's commitment to physicians by making advancements to proven technology. While EI-530B was not available in the US, the EC-450BI5 has the same functional design as the EI-530B, with the only difference being the image sensor. This publication shows that the new EI-580BT is even more beneficial than the previous versions for scope insertion with patients with altered anatomy as well as success rates in cannulation in certain populations. Fujifilm strives to continue to make it easier for physicians to accomplish their procedural goals by building on technology that works, and making it better.

1. Yamada A, Kogure H, Nakai Y, et al. 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. Digestive Endoscopy. 2019; 31: 86-930.1055/a-1216-1363

2. Tsutsumi K, Kato H, Okada H. Usefulness of short double-balloon enteroscopy for biliary intervention through Vater's papilla in a patient with Roux-en-Y gastrectomy. Dig. Enosc. 2017; 29: 642-3.