

EI-580BT in Clinical Studies

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Analysis of the Therapeutic Short Double Balloon Enteroscope Assisted Endoscopic Retrograde Cholangiopancreatography in Patients with Surgically-Altered Pancreaticobiliary Anatomy

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Background & Aim: Endoscopic Retrograde Cholangiopancreatography (ERCP) in patients with surgically-altered GI anatomy remains a technical challenge. Single balloon enteroscope (SBE) and double balloon enteroscope (DBE) assisted ERCP have been used with some limitations due to small working channel (2.8mm) and scope length (2300mm). The newly developed therapeutic short double-balloon enteroscope (T-sDBE) with 3.2 mm working channel and 1550 mm working length allows an easier handling of accessories designed for therapeutic ERCP. However, the existing data about this device is limited. This study aimed to assess the technical success of T-sDBE and compared it to conventional balloon-assisted enteroscope (C-BAE).

Methods: A retrospective study of ERCP database during 2009-2019. Patients with surgically-altered GI anatomy undergoing BAE-ERCP were reviewed. Types of BAE included T-sDBE (EI-580BT), and C-BAE including DBE (EN-580T) and SBE (SIF-Q180).

Definitions: enteroscopy success = able to reach ampulla, technical success = able to perform intervention, and clinical success = resolution of symptoms and normalization of bilirubin level.

Results: Forty-eight patients underwent 101 ERCP procedures: 75% C-BAE and 25% T-sDBE. The majority of surgical anatomy were Roux-En-Y hepaticojejunostomy (RYHJ) (55.4%), Whipple (23.8%), Billroth II (5.9%). The common diagnosis included bile duct stone (61.4%), anastomotic stricture (44.6%). The overall technical success rate was 62.4% (95% CI 52.5-72.3%), and clinical success rate was 59.4% (95%CI 49.5-69.3%). Seventy-eight interventions were performed including biliary stent insertion (90%), balloon dilation (28%), and stone extraction (18%). Adverse events occurred in 4% and all were post-ERCP cholangitis. When compared to the C-BAE, the T-sDBE was equivalent in terms of enteroscopy success (66.2% vs 72.0 %, $p=0.593$), and technical success (59.5% vs 68.0%, $p=0.448$) (Table 1). Among those with enteroscopy success, both T-sDBE and C-BAE provided high technical success of 94.4% and 89.8% ($p=1.0$) respectively. In patients with long limb such as RYHJ, the sDBE offered an equally good enteroscopy and technical success as C-BAE (75% Vs 71.1%, $p=1.0$ and 91.7% Vs 88.9%, $p=1.0$ respectively).

Conclusions: The T-sDBE was as effective as C-BAE in regard to enteroscopy success. However, an increased technical success was not demonstrated despite larger working channel in our study cohort where most of the interventions required was biliary stent placement for the treatment of biliary anastomotic stricture in RYHJ anatomy. Further studies are required to better assess the benefits of this new device.

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Table 1. Comparative analysis of T-sDBE and C-BAE

Variable	T-sDBE (N= 25)	C-BAE (N=74)	p value
Female gender	68.0%	60.8%	0.521
Age	52.36+/-18.95	54.18+/-15.11	0.961
BMI	21.41+/-2.36	22.47+/-3.82	0.110
Type of surgery			
Billroth II	4.0% (1/25)	6.8% (5/74)	0.293
Whipple	28.0% (7/25)	23.0% (17/25)	
Hepaticojejunostomy	64.0% (16/25)	51.4% (38/25)	
Other	4.0% (1/25)	18.9% (14/25)	
Technical success	68.0% (17/25)	59.5% (44/74)	0.448
Clinical success	68.0% (17/25)	55.4% (41/74)	0.269
Enteroscopy success	72.0% (18/25)	66.2% (25/74)	0.593
Procedure time (min)	94 +/- 41	107 +/- 47	0.242
Maximum stent diameter (Fr)	10.7+/- 3.55	8.3+/- 3.85	0.177
LOS (days)	4 +/- 3	5+/-6	0.419

FUJIFILM SUMMARY

Physicians struggle to treat patients with prior Roux-En-Y hepaticojejunostomy surgery due to the lengthened and tortuous path to the duodenum. Double Balloon scopes enable the physician to navigate through this anatomy, but the combination of the working channel diameter and the scope length of the previously marketed double and single balloon scopes make it impractical to pass the devices needed to deliver treatment. The EI-580BT Short Double Balloon has a 3.2 mm working channel and a length of 1550 mm, which is compatible with standard devices. This study shows the EI-580BT Short Double Balloon scope is at least equal to conventional balloon-assisted enteroscopy based on technical and clinical success.

Key Takeaways:

1. Short Double Balloon was equivalent to the previously marketed balloon scopes in terms of enteroscopy success (66.2% for sDBE vs 72.0 %, p=0.593).
2. In the subset of patients with enteroscopy success, high technical success was equivalent in both scope groups (94.4% for sDBE and 89.8%, p=1.0).
3. Technical success could not be fully challenged, because the size of the devices needed in the interventions were not challenging to the working channel diameter.

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