

Long-term outcomes of double-balloon endoscopy–assisted endoscopic balloon dilation for small bowel strictures in Crohn’s disease: a retrospective cohort study

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ABSTRACT

Crohn’s disease (CD) is a chronic, relapsing inflammatory disorder of the gastrointestinal tract characterized by transmural inflammation, often resulting in small bowel strictures. Although surgical resection remains the standard treatment, repeated surgeries increase the risk of short bowel syndrome. Endoscopic balloon dilation (EBD) has emerged as a less invasive alternative to surgery; however, its long-term efficacy and surgical predictors remain understudied. This study aimed to evaluate the long-term outcomes, safety, and risk factors of surgery following double-balloon endoscopy (DBE)–assisted EBD (DBE-EBD) in patients with CD. This study retrospectively analyzed 177 patients with CD who underwent DBE for small-bowel strictures at Nagoya University Hospital between March 2004 and January 2024. Among the 120 eligible patients, EBD was attempted in 68. Technical success (passage of a 9.4-mm endoscope) was achieved in 55 (80.9%) of them. The cumulative surgery-free rates were 89.7% at 1 year and 79.8% at 3 years, whereas the redilation-free rates were 72.4% and 43.4%, respectively. Patients who underwent successful EBD showed significantly higher surgery-free survival than those who underwent unsuccessful EBD (1-year rate, 94.5% vs 69.2%, $p = 0.002$). Multivariate analysis identified unsuccessful EBD as the sole independent risk factor for subsequent surgery. No significant predictors of redilation or emergency hospitalization were identified. DBE-EBD for small-bowel strictures in CD demonstrates high rates of technical success and long-term surgery-free survival. Unsuccessful EBD was the strongest predictor of subsequent surgery, highlighting the importance of procedural success. Therefore, DBE-EBD appears to be a valuable bowel-preserving strategy in appropriately selected patients.

Keywords: Crohn’s disease, endoscopic balloon dilation, double-balloon endoscopy, small bowel stricture, surgery avoidance

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INTRODUCTION

Crohn's disease (CD) is a chronic, progressive inflammatory disorder that can affect any part of the gastrointestinal tract. Recurrent cycles of inflammation and healing frequently lead to intestinal fibrosis and stricture formation, particularly in the small intestine.^{1,2} These strictures may cause obstructive symptoms such as abdominal pain, distension, and vomiting, substantially impairing patients' quality of life.^{3,4}

Surgical resection has long been the mainstay of treatment for symptomatic small bowel strictures. However, repeated surgeries inevitably shorten the intestine and can result in malnutrition or short bowel syndrome. Therefore, bowel-preserving strategies have become central to long-term CD management.^{5,6} Recently, the therapeutic paradigm has shifted from reactive surgery to proactive, minimally invasive management that aims to preserve intestinal function and sustain quality of life. The concept of bowel preservation underpins modern care of inflammatory bowel disease (IBD) and complements the evolution of biological and endoscopic therapies.⁷

Endoscopic balloon dilation (EBD) has gained widespread acceptance as a less-invasive alternative to surgery, particularly for short fibrotic strictures without deep ulceration or fistula formation. The advent of balloon-assisted enteroscopy, especially double-balloon endoscopy (DBE), has enabled direct access to deep small bowel lesions that were previously unreachable using conventional methods. A nationwide prospective study by Hirai et al demonstrated that DBE-assisted EBD (DBE-EBD) is effective and safe, achieving a technical success rate of 93.7% with symptomatic improvement in approximately 70% of patients.⁸ Furthermore, long-term studies, including that by Ohmiya et al, have shown that DBE-EBD can delay the need for surgery in many cases.⁹

In a Japanese multicenter cohort of 305 patients with CD who had symptomatic small bowel strictures and no prior surgery, factors such as non-penetrating disease phenotype, mild symptoms, short stricture length (≤ 2 cm), use of immunomodulators or anti-tumor necrosis factor (anti-TNF) agents, and successful EBD were associated with surgery avoidance.¹⁰ This finding underscores the potential of the procedure to prevent future operations.

Despite these advances, the long-term outcomes of DBE-EBD and clinical predictors of surgery or redilation remain unclear. Clarifying these factors would refine patient selection and optimize endoscopic treatment strategies. Therefore, this study aimed to evaluate the long-term efficacy and safety of DBE-EBD for small bowel strictures in patients with CD and to identify the risk factors associated with subsequent surgery.

METHODS

Study design and patients

This retrospective cohort study was conducted at the Nagoya University Hospital. This study reviewed the medical records of 177 consecutive patients with CD who underwent DBE for small bowel strictures between March 2004 and January 2024. Patients with a follow-up period of less than 12 months were excluded from the analysis. This study was approved by the Institutional Review Board, and informed consent for the endoscopic procedures was obtained from all patients.

At our institution, the general indication for DBE-EBD is the presence of symptomatic endoscopically accessible small bowel strictures. Patients were typically considered for direct surgical resection if the stricture was deemed unsuitable for endoscopic intervention. Unsuitability for EBD was determined by the presence of contraindications, such as stricture length >5 cm,

deep ulceration, fistula, abscess, or strong bowel flexion that would preclude safe dilation.

Inclusion criteria. It provided as follows:

1. Presence of symptomatic small bowel strictures that could not be traversed by the endoscope
2. Presence of obstructive symptoms attributable to stricture (eg, recurrent postprandial abdominal pain, nausea, vomiting, or abdominal distension)

Exclusion criteria. Three criteria were used:

1. Presence of fistula or deep ulcer at the stricture site
2. Stricture length exceeding 5 cm
3. Marked bowel angulation or configuration precluding safe dilation

DBE-EBD procedure

All DBE procedures were performed under conscious sedation using standard techniques.^{9,11,12} The procedures were performed using a Fujifilm EN-450T or EN-580T enteroscope and a controlled radial expansion balloon catheter (CRE balloon; Boston Scientific, Marlborough, MA, USA). Once the enteroscope reached the responsible stricture, it was visually inspected for diameter and any contraindicating features, such as deep ulcers or fistulas. Subsequently, contrast radiography with Gastrografin was performed to measure the stricture length and exclude any leaks. If the stricture was deemed suitable for EBD, a balloon dilator with an appropriate diameter, selected based on visual estimation, was used for the initial dilation. The balloon was inflated and maintained for 60 seconds. After each dilation, the site was evaluated for procedural complications, and an attempt was made to pass the endoscope through the stricture. In cases of failed passage, dilation was repeated with progressively larger balloons until successful passage was achieved, or the procedure was terminated if further dilation was considered unsafe owing to adverse events such as significant bleeding or mucosal tears. The number of strictures treated, the maximum dilation diameter, and procedural complications were recorded.

Clinical outcomes and definitions

The primary endpoints were surgery-free, redilation-free, intervention-free, symptomatic relapse-free, and emergency hospitalization-free rates 12 months after the initial EBD. The rates at 36 months were assessed as the secondary endpoints.

These clinical outcomes were defined as follows.

- Surgery-free rate: proportion of patients who avoided intestinal resection after the initial EBD
- Redilation-free rate: proportion of patients who did not require repeat EBD
- Intervention-free rate: proportion of patients who avoided subsequent surgery and redilation
- Symptomatic relapse-free rate: proportion of patients without the recurrence of obstructive symptoms necessitating urgent endoscopic or radiological evaluation
- Emergency hospitalization-free rate: proportion of patients avoiding hospitalization for obstructive symptoms

Complications, including perforation and bleeding, were also recorded. Follow-up data were obtained from medical records and outpatient visits

In this study, the key term, technical success of EBD, was defined as successful passage of the 9.4-mm enteroscope through the stricture post-dilation. In cases classified as technical failures, the inability to pass the endoscope was primarily due to the termination of the procedure because further dilation was considered unsafe in the presence of adverse events such as significant bleeding or deep mucosal tears. The degree of symptoms was categorized into three grades: “mild” for symptoms under control, “moderate” for symptoms causing an unscheduled outpatient visit, and “severe” for symptoms requiring emergency hospitalization.

Statistical analysis

Kaplan–Meier survival analysis was used to estimate the cumulative surgery-free, redilation-free, intervention-free, relapse-free, and hospitalization-free rates. Differences between groups were evaluated using the log-rank test. Cox proportional hazards regression models with backward stepwise selection were used to identify the independent predictors of surgery, redilation, intervention, symptomatic relapse, and emergency hospitalization. For comparisons of baseline characteristics between groups, the Mann-Whitney *U* test was used for continuous variables, and Fisher's exact test was used for categorical variables. Statistical significance was set at $p < 0.05$. All statistical analyses were performed using SPSS software (version 28.0; IBM Corp, Armonk, NY, USA).

Ethical considerations

The study was conducted in accordance with the principles of Declaration of Helsinki. The study protocol was designed as a retrospective analysis of clinical data, and patient information was disclosed using the opt-out method on our institution's website. This process provided patients with the opportunity to decline participation. All data were fully anonymized before the analysis to protect patient privacy.

RESULTS

Patient and stricture characteristics

Of the 177 patients initially identified, 57 were excluded due to insufficient follow-up (<12 months), leaving 120 patients for analysis. EBD was attempted in 68 patients and completed in 55 patients, yielding a technical success rate of 80.9% (Figure 1). EBD was not performed in the remaining 52 patients for the following reasons: failure to reach the stricture ($n = 5$), presence of a fistula at the stricture site ($n = 1$), presence of deep ulcers ($n = 34$), stricture length > 5 cm ($n = 4$), or strong flexion ($n = 8$).

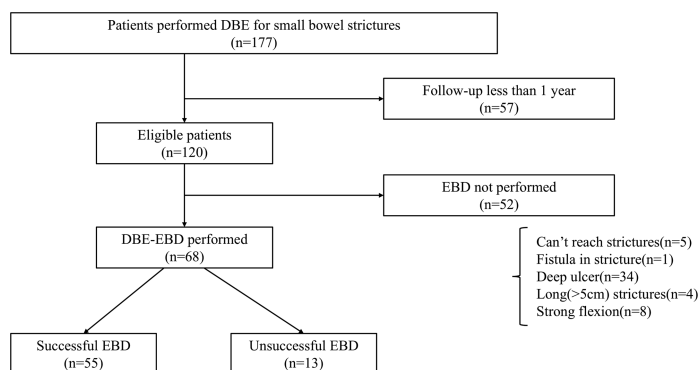


Fig. 1 Flow diagram of patient inclusion and exclusion

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

Sixty-eight patients who underwent DBE-EBD were included in the final analysis. Baseline patient and stricture characteristics are summarized in Table 1. The median patient age was 39 years (range, 17–84 years), and the median disease duration was 106 months (range, 1–605

months). Most patients were male (69.1%), had ileal disease (L1, 65%), and had a history of intestinal resection (54%). At the time of the procedure, 37% of the patients were receiving biologics, and 35% were receiving immunomodulators. The median number of strictures per patient was 2 (range, 1–18). The target stricture was located in the ileum in 52% of the cases and at the anastomosis in 31%.

Table 1 Baseline characteristics of the patients (n = 68)

Characteristic	n (%) or median (range)
Sex (male/female)	47/21
Age at DBE, median (range), years	39 (17–84)
Disease duration, median (range), months	106 (1–605)
Observation period, median (range), months	62 (12–205)
Disease location (L1/L2/L3)	44 (65%)/0/24 (35%)
Perianal disease	20 (29%)
Biologics use	25 (37%)
Immunomodulator use	24 (35%)
History of surgery	37 (54%)
Degree of symptoms (mild/moderate/severe)	36 (53%)/13 (19%)/19 (28%)
Location of stricture (jejunum/ileum/anastomosis)	12 (17%)/35 (52%)/21 (31%)
Number of strictures, median (range)	2 (1–18)
Stricture length ≥ 2 cm	10 (15%)
Ulcer on stricture (none/partly/whole circumference)	46 (68%)/20 (29%)/2 (3%)
Total enteroscopy	7 (10%)
Technical success of EBD	55 (81%)

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

Procedural outcomes and safety

The 68 patients were divided into technical success (n = 55) and technical failure (n = 13) groups. There were no significant differences in any baseline patient or stricture characteristics between the two groups (Table 2).

Technical success, defined as the ability to pass the endoscope through the dilated stricture, was achieved in 55 of the 68 patients (80.9%). Procedure-related adverse events occurred in two patients (2.9%). These included one case of perforation at a site other than the dilated area and one case of acute pancreatitis. Both patients recovered with conservative management.

Table 2 Comparison of patient characteristics between successful and unsuccessful EBD groups

Characteristic	Successful EBD (n = 55) n (%) or median (range)	Unsuccessful EBD (n = 13) n (%) or median (range)	<i>p</i>
Sex			
Male	37 (67%)	10 (77%)	
Female	18 (33%)	3 (23%)	0.740**
Age at DBE, years	39 (17–66)	39 (21–84)	0.640*
Disease duration, months	109 (1–605)	100 (10–466)	0.827*
Observation period, months	58 (12–205)	72 (13–199)	0.755*
Disease location			
L1	36 (66%)	11 (85%)	
L3	19 (34%)	2 (15%)	0.317**
Perianal disease	16 (29%)	4 (31%)	1.000**
Biologics use	20 (36%)	5 (39%)	1.000**
Introduction/change of biologics after EBD	17 (31%)	3 (23%)	0.741**
Immunomodulator use	18 (33%)	6 (46%)	0.520**
History of surgery	32 (58%)	5 (39%)	0.230**
Degree of symptoms			
Mild	30 (55%)	6 (46%)	
Moderate	10 (18%)	3 (23%)	
Severe	15 (27%)	4 (31%)	0.773**
Location of stricture			
Jejunum	10 (18%)	2 (15%)	
Ileum	26 (47%)	9 (69%)	
Anastomosis	19 (35%)	2 (15%)	0.321**
Number of strictures	1 (1–18)	2 (1–6)	0.829*
Stricture length ≥2 cm	8 (10%)	2 (12%)	0.907**
Ulcer on stricture			
None	27 (54%)	11 (61%)	
Partly circumference	18 (36%)	7 (39%)	
Whole circumference	5 (10%)	0 (0%)	0.380**
Total enteroscopy	7 (13%)	0 (0%)	0.331**

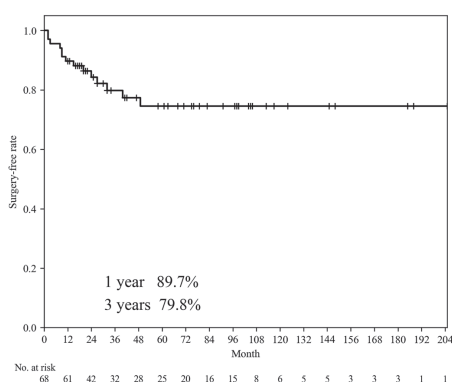
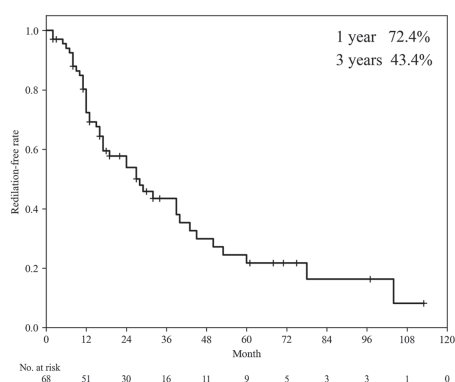
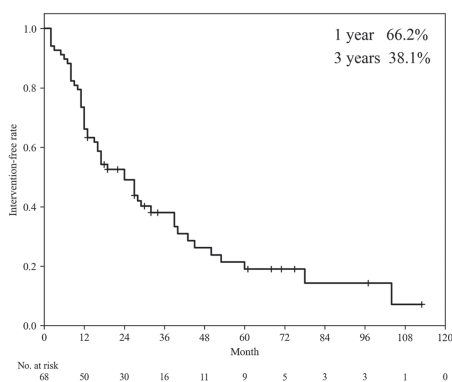
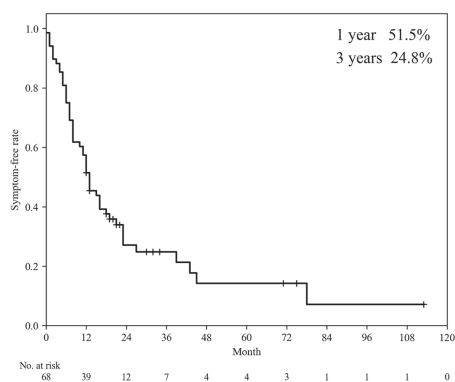
DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

* Mann-Whitney *U* test, ** Fisher's exact test.

Long-term outcomes

The median follow-up period was 62 months (range, 12–205). The cumulative surgery-free rate (primary endpoint) was 89.7% at 1 year. The 3-year rate (secondary endpoint) was 79.8%. The redilation-free rates were 72.4% and 43.4% at 1 year and 3 years, respectively. The intervention-free rates were 66.2% at 1 year and 38.1% at 3 years. The symptom-free rates were 51.5% and 24.8% at 1 and 3 years, respectively. The hospitalization-free rates were 63.2% at one year and 34.5% at 3 years (Figures 2–6). Patients with successful EBD demonstrated a significantly higher surgery-free survival than those with unsuccessful EBD (1-year rate, 94.5% vs 69.2%; $p = 0.002$) (Figure 7). The other outcomes, including redilation-free, intervention-free, symptom-free, and hospitalization-free rates, did not differ significantly between the groups (Figures 8–11).

**Fig. 2** Cumulative surgery-free rate**Fig. 3** Cumulative redilation-free rate**Fig. 4** Cumulative intervention-free rate**Fig. 5** Cumulative symptom-free rate

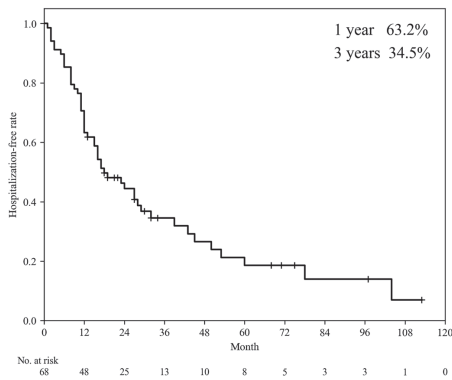


Fig. 6 Cumulative hospitalization-free rate

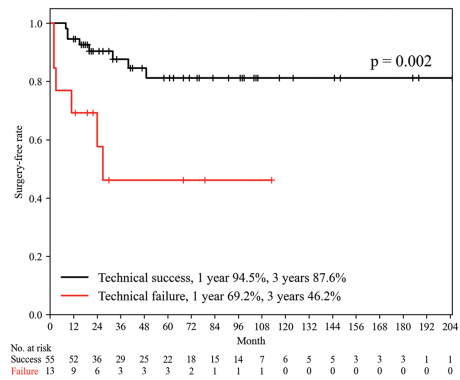


Fig. 7 Cumulative surgery-free rates according to EBD success ($p = 0.002$, log-rank test)
EBD: endoscopic balloon dilation

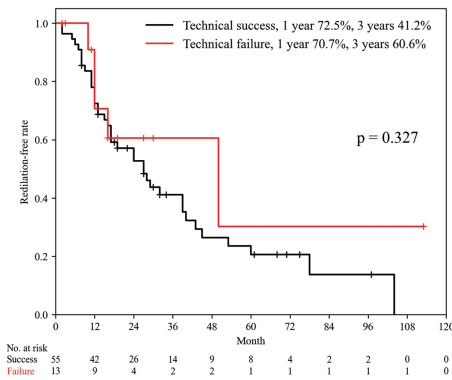


Fig. 8 Cumulative redilation-free rates according to EBD success ($p = 0.327$, log-rank test)
EBD: endoscopic balloon dilation

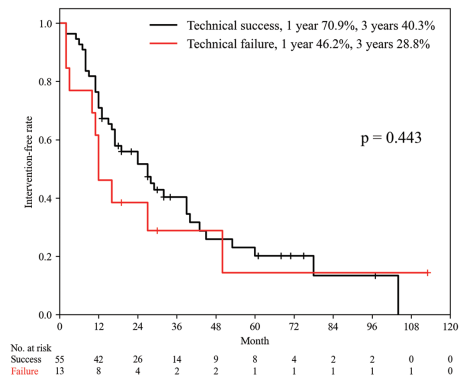


Fig. 9 Cumulative intervention-free rates according to EBD success ($p = 0.443$, log-rank test)
EBD: endoscopic balloon dilation

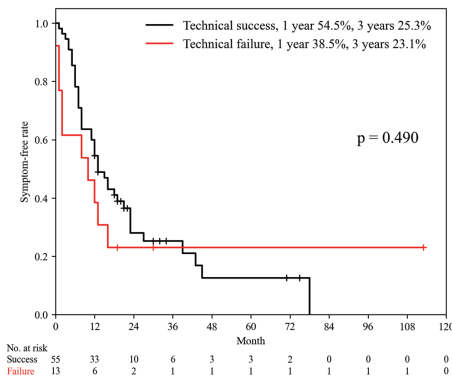


Fig. 10 Cumulative symptom-free rates according to EBD success ($p = 0.490$, log-rank test)
EBD: endoscopic balloon dilation

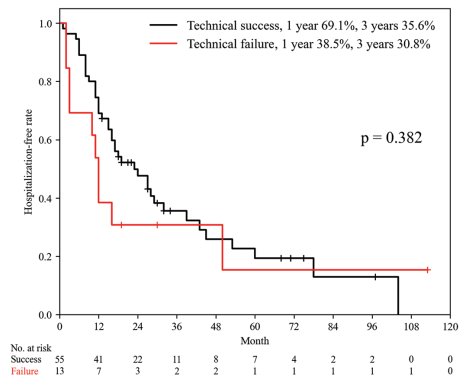


Fig. 11 Cumulative hospitalization-free rates according to EBD success ($p = 0.382$, log-rank test)
EBD: endoscopic balloon dilation

Risk factor analysis

In the multivariate Cox proportional hazards analysis, technical failure was identified as a significant independent risk factor for subsequent surgery (hazard ratio [HR], 0.220 for technical success; 95% confidence interval [CI], 0.08–0.64; $p = 0.005$) (Table 3). For symptom relapse, a pre-procedural symptom degree of moderate or severe was found to be a significant independent risk factor (HR, 1.964; 95% CI, 1.13–3.40; $p = 0.016$) (Table 6). In the multivariate analyses of redilation, intervention, and emergency hospitalization, no significant independent risk factors were identified (Tables 4, 5, 7).

Table 3 Risk factors for surgery after DBE-EBD of the patients (n = 68)

Variable		Univariate			Multivariate		
		HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Sex	Male	1					
	Female	1.242	0.42–3.71	0.698			
Disease location	L1	1					
	L3	0.510	0.14–1.83	0.302			
Perianal disease	No	1					
	Yes	0.544	0.15–1.96	0.352			
Biologics use	No	1					
	Yes	0.862	0.27–2.78	0.804			
History of surgery	No	1					
	Yes	0.569	0.20–1.64	0.297			
Degree of symptom	Mild	1					
	Moderate or severe	1.397	0.48–4.04	0.536			
Location of stricture	De novo	1					
	Anastomosis	0.650	0.18–2.34	0.510			
Stricture length	<2 cm	1					
	≥2 cm	1.220	0.34–4.40	0.761			
Diameter of lumen	<5 mm	1					
	≥5 mm	1.894	0.59–6.05	0.281			
Ulcers on stricture	No	1					
	Yes	1.729	0.60–5.02	0.314			
Number of strictures	Single	1					
	Multiple	1.280	0.44–3.70	0.648			
Total enteroscopy	No	1					
	Yes	1.421	0.32–6.37	0.646			
Technical success	No	1			1		
	Yes	0.220	0.08–0.64	0.005	0.220	0.08–0.64	0.005
Maximum dilatation	<15 mm	1					
	≥15 mm	1.011	0.35–2.95	0.984			

CI: confidence interval

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

HR: hazard ratio

Table 4 Risk factors for redilation after DBE-EBD of the patients (n = 68)

Variable		Univariate			Multivariate		
		HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Sex	Male	1					
	Female	1.136	0.58–2.23	0.712			
Disease location	L1	1					
	L3	0.671	0.34–1.31	0.241			
Perianal disease	No	1					
	Yes	1.140	0.61–2.13	0.682			
Biologics use	No	1					
	Yes	0.983	0.52–1.87	0.958			
History of surgery	No	1					
	Yes	0.847	0.47–1.54	0.588			
Degree of symptom	Mild	1					
	Moderate or severe	1.197	0.66–2.18	0.556			
Location of stricture	De novo	1					
	Anastomosis	1.007	0.52–1.94	0.982			
Stricture length	<2 cm	1					
	≥2 cm	1.166	0.52–2.63	0.711			
Diameter of lumen	<5 mm	1					
	≥5 mm	0.712	0.39–1.30	0.266			
Ulcers on stricture	No	1					
	Yes	1.294	0.70–2.38	0.408			
Number of strictures	Single	1					
	Multiple	1.208	0.66–2.20	0.537			
Total enteroscopy	No	1					
	Yes	0.791	0.28–2.22	0.656			
Technical success	No	1					
	Yes	1.590	0.62–4.06	0.337			
Maximum dilatation	<15 mm	1					
	≥15 mm	0.606	0.31–1.18	0.143			

CI: confidence interval

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

HR: hazard ratio

Table 5 Risk factors for intervention after DBE-EBD of the patients (n = 68)

Variable		Univariate			Multivariate		
		HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Sex	Male	1					
	Female	1.018	0.54–1.93	0.958			
Disease location	L1	1					
	L3	0.687	0.37–1.28	0.236			
Perianal disease	No	1					
	Yes	1.031	0.57–1.87	0.921			
Biologics use	No	1					
	Yes	0.907	0.49–1.67	0.753			
History of surgery	No	1					
	Yes	0.825	0.47–1.45	0.502			
Degree of symptom	Mild	1					
	Moderate or severe	1.389	0.79–2.44	0.251			
Location of stricture	De novo	1					
	Anastomosis	0.911	0.49–1.70	0.770			
Stricture length	<2 cm	1					
	≥2 cm	1.152	0.54–2.47	0.716			
Diameter of lumen	<5 mm	1					
	≥5 mm	0.778	0.44–1.37	0.382			
Ulcers on stricture	No	1					
	Yes	1.400	0.79–2.47	0.246			
Number of strictures	Single	1					
	Multiple	1.200	0.68–2.10	0.525			
Total enteroscopy	No	1					
	Yes	0.676	0.24–1.88	0.454			
Technical success	No	1					
	Yes	0.764	0.38–1.54	0.452			
Maximum dilatation	<15 mm	1					
	≥15 mm	0.622	0.33–1.16	0.135			

CI: confidence interval

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

HR: hazard ratio

Table 6 Risk factors for symptomatic relapse after DBE-EBD of the patients (n = 68)

Variable		Univariate			Multivariate		
		HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Sex	Male	1					
	Female	0.547	0.29–1.05	0.069			
Disease location	L1	1					
	L3	0.994	0.55–1.81	0.984			
Perianal disease	No	1					
	Yes	0.971	0.54–1.74	0.921			
Biologics use	No	1					
	Yes	0.803	0.44–1.46	0.472			
History of surgery	No	1					
	Yes	1.218	0.70–2.11	0.482			
Degree of symptom	Mild	1			1		
	Moderate or severe	1.964	1.13–3.40	0.016	1.964	1.13–3.40	0.016
Location of stricture	De novo	1					
	Anastomosis	0.847	0.46–1.55	0.589			
Stricture length	<2 cm	1					
	≥2 cm	1.816	0.91–3.64	0.092			
Diameter of lumen	<5 mm	1					
	≥5 mm	0.799	0.46–1.39	0.427			
Ulcers on stricture	No	1					
	Yes	1.376	0.78–2.42	0.268			
Number of strictures	Single	1					
	Multiple	0.942	0.55–1.63	0.829			
Total enteroscopy	No	1					
	Yes	0.669	0.26–1.69	0.396			
Technical success	No	1					
	Yes	0.787	0.39–1.58	0.501			
Maximum dilatation	<15 mm	1					
	≥15 mm	1.115	0.63–1.96	0.707			

CI: confidence interval

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

HR: hazard ratio

Table 7 Risk factors for emergency rehospitalization after DBE-EBD of the patients (n = 68)

Variable		Univariate			Multivariate		
		HR	95% CI	<i>p</i>	HR	95% CI	<i>p</i>
Sex	Male	1					
	Female	0.782	0.41–1.51	0.462			
Disease location	L1	1					
	L3	0.627	0.33–1.19	0.151			
Perianal disease	No	1					
	Yes	0.944	0.52–1.71	0.851			
Biologics use	No	1					
	Yes	0.929	0.50–1.72	0.814			
History of surgery	No	1					
	Yes	1.024	0.58–1.80	0.934			
Degree of symptom	Mild	1					
	Moderate or severe	1.448	0.83–2.54	0.197			
Location of stricture	De novo	1					
	Anastomosis	0.882	0.47–1.64	0.692			
Stricture length	<2 cm	1					
	≥2 cm	1.231	0.57–2.64	0.593			
Diameter of lumen	<5 mm	1					
	≥5 mm	0.774	0.44–1.36	0.372			
Ulcers on stricture	No	1					
	Yes	1.365	0.77–2.41	0.284			
Number of strictures	Single	1					
	Multiple	1.021	0.58–1.79	0.941			
Total enteroscopy	No	1					
	Yes	0.960	0.38–2.45	0.932			
Technical success	No	1					
	Yes	0.735	0.36–1.48	0.390			
Maximum dilatation	<15 mm	1					
	≥15 mm	0.739	0.40–1.36	0.330			

CI: confidence interval

DBE: double-balloon endoscopy

EBD: endoscopic balloon dilation

HR: hazard ratio

DISCUSSION

This study demonstrated that DBE-EBD is a safe and effective therapeutic option for small bowel strictures in patients with CD. The observed technical success rate (80.9%) and 1-year surgery-free rate (89.7%) were comparable to or slightly superior to those reported in previous large-scale studies.¹³⁻¹⁷ These results support the role of DBE-EBD as a key bowel-preserving strategy for managing CD-related strictures in selected patients.

The multivariate analysis identified technical success as a pivotal predictor of long-term outcomes, superseding the baseline clinical characteristics. This underscores that the procedural outcome itself, rather than preexisting factors, is critical. Notably, although previous reports have identified stricture length and ulceration as prognostic indicators,¹⁸ these variables were not significant in our cohort. This is likely attributable to our careful patient selection and technical refinement,¹⁹ which may have created a more homogeneous patient group for analysis. This finding highlights the importance of preprocedural imaging assessment, selection of the optimal dilation diameter, and procedural expertise in achieving technical success, which dictates long-term prognosis.

In contrast, technically unsuccessful procedures often result in complex strictures with severe fibrosis or angulation, which are less amenable to mechanical dilation and may inherently carry a higher surgical risk. Although initial technical failure might influence subsequent therapeutic choices, it was not considered an absolute reason to proceed directly with surgery upon recurrence. Our institutional principle is to consider EBD as the first-line option for any restriction that meets the therapeutic criteria at the time of diagnosis. Surgery is generally reserved for patients with factors that make repeat EBD unsuitable, such as unreachable strictures. The final treatment modality for each patient was determined through multidisciplinary discussions within the IBD team, which included gastroenterologists and surgeons. Through this process, cases of initial failure are often reevaluated as having complex features unsuitable for another endoscopic attempt, leading to a strong association with subsequent surgery.

Furthermore, it is important to consider the potential bias related to technical failure. As the primary reason for failure was the termination of the procedure for safety reasons, these cases are likely to represent more severe or fragile strictures. This allocation may have inherently contributed to the higher rate of subsequent surgery in the technical failure group, as these patients may have been considered as high-risk surgical candidates from the outset.

The endpoint of 'surgery-free survival' requires careful interpretation in the context of modern CD care. Far from therapeutic failure, timely surgical intervention can be highly effective in improving the quality of life. Consequently, 'surgery-free survival' should not be viewed as the sole measure of success. Instead, long-term management often focuses on preserving intestinal length. The primary concern with repeated surgeries is the progressive loss of bowel length, which can lead to short bowel syndrome, a severe complication that profoundly diminishes a patient's quality of life. From this perspective, the value of EBD lies in its function as bowel-preserving therapy. The goal is to extend the time until the next necessary resection, thereby preventing the onset of short bowel syndrome. Therefore, these findings support EBD as a strategic intervention to prolong the surgery-free interval rather than as a replacement for definitive surgical treatment when necessary.

Approximately half of the patients required redilation within 3 years, emphasizing that long-term stricture patency remains a clinical challenge. This high rate of recurrence was expected, as CD is an inherently fibrotic disease in which stricture reformation is common even after technically successful dilation. Therefore, combining endoscopic intervention with optimized medical therapy, including biologics targeting the TNF- α or interleukin (IL)-23 pathways, may help

sustain stricture patency and delay surgery.^{20,21} Recent prospective studies and machine learning approaches have suggested that integrated models combining endoscopic and pharmacological data can improve the prediction of restenosis risk.^{22,23}

This study's strengths include a relatively large cohort, an extended observation period, and a comprehensive assessment of long-term outcomes. However, this study had several limitations. First, the retrospective single-center design may have introduced a potential selection bias. Second, the follow-up intervals and medical treatments were not fully standardized. Third, a histological evaluation of the stricture tissue was not performed. Fourth, this study lacked a control group of patients with small bowel strictures who were managed without EBD. This is an inherent limitation of the retrospective design. Specifically, patients in our cohort who did not undergo EBD were those in whom the stricture was unreachable or had contraindications, such as deep ulceration or fistulas. This represents a clinically different population, and a direct comparison would introduce a significant selection bias. Therefore, these results should be interpreted as a description of outcomes following EBD rather than as a direct comparison of its efficacy with other treatments. Finally, the long study period of 20 years spans a significant evolution in the medical management of CD. Although the analysis showed that the use of biologics or immunomodulators at baseline was not an independent predictor of outcomes, such as the need for surgery or redilation, the evolution of medical therapies represents a potential confounding factor. The introduction of new biological agents with different mechanisms of action and the general shift in treatment paradigms during this period may have influenced the long-term patency of dilated strictures. This study was not powered enough to perform a stratified analysis by treatment era, which is a limitation. Future multicenter prospective trials are warranted to establish standardized EBD protocols and to define the optimal timing and combination strategies within a broader therapeutic framework for CD.

CONFLICT OF INTEREST

The authors declare that there are no competing interests.

REFERENCES

- 1 Watanabe K. Clinical management for small bowel of Crohn's disease in the treat-to-target era: now is the time to optimize treatment based on the dominant lesion. *Intest Res*. 2020;18(4):347–354. doi:10.5217/ir.2020.00032
- 2 Takenaka K, Ohtsuka K, Kitazume Y, et al. Magnetic resonance evaluation for small bowel strictures in Crohn's disease: comparison with balloon enteroscopy. *J Gastroenterol*. 2017;52(8):879–888. doi:10.1007/s00535-016-1284-z
- 3 Hu J, Wu J, Zhang P, et al. Evaluation of symptomatic small bowel stricture in Crohn's disease by double-balloon endoscopy. *BMC Gastroenterol*. 2023;23(1):247. doi:10.1186/s12876-023-02839-8
- 4 Gordon H, Minozzi S, Kopylov U, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment. *J Crohns Colitis*. 2024;18(10):1531–1555. doi:10.1093/ecco-jcc/jjae033
- 5 Meima-van Praag EM, Buskens CJ, Hompes R, Bemelman WA. Surgical management of Crohn's disease: a state of the art review. *Int J Colorectal Dis*. 2021;36(6):1133–1145. doi:10.1007/s00384-021-03857-2
- 6 Lee KE, Cantrell S, Shen B, Faye AS. Post-operative prevention and monitoring of Crohn's disease recurrence. *Gastroenterol Rep (Oxf)*. 2022;10:goac070. doi:10.1093/gastro/goac070
- 7 Panés J, Rimola J. Perianal Crohn's disease: pathogenesis, diagnosis and therapy. *Nat Rev Gastroenterol Hepatol*. 2017;14(11):652–664. doi:10.1038/nrgastro.2017.104
- 8 Hirai F, Andoh A, Ueno F, et al. Efficacy of Endoscopic Balloon Dilation for Small Bowel Strictures in Patients With Crohn's Disease: A Nationwide, Multi-centre, Open-label, Prospective Cohort Study. *J Crohns Colitis*. 2018;12(4):394–401. doi:10.1093/ecco-jcc/jjx159

- 9 Ohmiya N, Arakawa D, Nakamura M, et al. Small-bowel obstruction: diagnostic comparison between double-balloon endoscopy and fluoroscopic enteroclysis, and the outcome of enteroscopic treatment. *Gastrointest Endosc.* 2009;69(1):84–93. doi:10.1016/j.gie.2008.04.067
- 10 Bamba S, Sakemi R, Fujii T, et al. A nationwide, multi-center, retrospective study of symptomatic small bowel stricture in patients with Crohn's disease. *J Gastroenterol.* 2020;55(6):615–626. doi:10.1007/s00535-020-01670-2
- 11 Kawamura T, Yamamura T, Nakamura M, et al. Accuracy of Serum Leucine-Rich Alpha-2 Glycoprotein in Evaluating Endoscopic Disease Activity in Crohn's Disease. *Inflamm Bowel Dis.* 2023;29(2):245–253. doi:10.1093/ibd/izac076
- 12 Tanaka H, Nakamura M, Yamamura T, et al. A newly proposed endoscopic score system to evaluate the entire small bowel and predict the prognosis in Crohn's disease. *Nagoya J Med Sci.* 2024;86(4):608–619. doi:10.18999/nagjms.86.4.608
- 13 Bettenworth D, Gustavsson A, Atreja A, et al. A Pooled Analysis of Efficacy, Safety, and Long-term Outcome of Endoscopic Balloon Dilation Therapy for Patients with Strictureing Crohn's Disease. *Inflamm Bowel Dis.* 2017;23(1):133–142. doi:10.1097/MIB.0000000000000988
- 14 Moond V, Gill VJS, Malik S, et al. Endoscopic dilation of small-intestine strictures in Crohn's disease by balloon-assisted enteroscopy: a systematic review and meta-analysis. *Ann Gastroenterol.* 2024;37(6):682–694. doi:10.20524/aog.2024.0920
- 15 Bettenworth D, Bokemeyer A, Kou L, et al. Systematic review with meta-analysis: efficacy of balloon-assisted enteroscopy for dilation of small bowel Crohn's disease strictures. *Aliment Pharmacol Ther.* 2020;52(7):1104–1116. doi:10.1111/apt.16049
- 16 Hong SN, Kim JE, Kim ER, Chang DK, Kim YH. Enteroscopic Balloon Dilation in Small Bowel Strictureing Crohn's Disease: Long-Term Outcomes and Risk Factors for Surgery in a Single-Center Prospective Observational Study. *United European Gastroenterol J.* 2025;13(6):958–970. doi:10.1002/ueg2.12775
- 17 Su T, Lu Y, Lan N, et al. Prediction of endoscopic restenosis after endoscopic balloon dilation in patients with Crohn's disease: a machine learning approach. *Surg Endosc.* 2025;39(6):3896–3910. doi:10.1007/s00464-025-11751-z
- 18 Yamamoto H, Yano T, Araki A, et al. Guidelines for endoscopic balloon dilation in treating Crohn's disease-associated small intestinal strictures (supplement to the Clinical Practice Guidelines for Enteroscopy). *Dig Endosc.* 2022;34(7):1278–1296. doi:10.1111/den.14429
- 19 Matsumoto T, Hisamatsu T, Esaki M, et al. Guidelines for endoscopic diagnosis and treatment of inflammatory bowel diseases. *Dig Endosc.* 2025;37(4):319–351. doi:10.1111/den.15002
- 20 Takeda T, Kishi M, Takatsu N, et al. Long-term outcomes of endoscopic balloon dilation for intestinal strictures in patients with Crohn's disease during maintenance treatment with anti-tumor necrosis factor alpha antibodies. *Dig Endosc.* 2022;34(3):517–525. doi:10.1111/den.14073
- 21 Murate K, Nakamura M, Fujishiro M. A Case Where Administration of Ustekinumab Maintained the Intestinal Patency After Balloon Dilation for Small Intestinal Stenosis Caused by Crohn's Disease. *Inflamm Bowel Dis.* 2019;25(11):e140. doi:10.1093/ibd/izz166
- 22 Xiong Z, Gong P, Meng T, et al. Machine learning-based prediction of response to Ustekinumab with Crohn's disease. *Therap Adv Gastroenterol.* 2025;18:17562848251382749. doi:10.1177/17562848251382749
- 23 Xia P, Deng F, Liu D. Development and validation of a machine learning-based predictive model for clinical remission in Crohn's disease patients receiving Adalimumab therapy. *PLoS One.* 2025;20(9):e0331447. doi:10.1371/journal.pone.0331447