Surgical Endoscopy (2024) 38:1775–1783
https://doi.org/10.1007/s00464-023-10661-2

Risk factors for the failure of endoscopic balloon dilation to manage anastomotic stricture from colorectal surgery: retrospective cohort study

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Received: 3 November 2023 / Accepted: 22 December 2023 / Published online: 26 January 2024

Abstract

Background An anastomotic stricture after colorectal surgery is principally managed by endoscopic balloon dilation (EBD). Although this intervention is effective, however, subsequent procedures or surgical interventions are often required. This study aimed to assess the long-term outcomes of EBD for anastomotic stricture arising from colorectal cancer surgery.

Materials and methods We analyzed 173 patients who received curative surgery for colorectal cancer at our hospital between January 2000 and December 2022 and had undergone EBD to manage anastomotic stricture. The medical records of these cases were retrospectively reviewed to assess the outcomes and risk factors for restenosis and permanent stoma.

Results Of the 173 study patients, 41 (23.7%) presented with restenosis with a median time to recurrence of 49 [37–150] days. The restenosis group was significantly younger (55.6 years versus 60.8 years), with a more prominent rectal location (80.5% versus 57.6%), a higher incidence of hand-sewn anastomosis (24.4% versus 5.3%), and a higher percentage of neoadjuvant radiotherapy (34.1% versus 5.3%, $P<0.001$). Multivariable analysis indicated neoadjuvant radiotherapy (adjusted HR 2.48; 95% CI 1.03–5.95) and cerebral vascular disease (adjusted HR 6.97; 95% CI 2.15–22.54) as independent prognostic factors for restenosis. Fourteen patients (8.1%) required a permanent stoma due to treatment failure. All cases needing a permanent stoma were male (14 patients, 100%, $P=0.007$) and this group had a higher rate of neoadjuvant radiotherapy, adjuvant chemotherapy, and hand-sewn anastomosis.

Conclusion Patients receiving neoadjuvant radiotherapy are most prone to restenosis after an EBD intervention to manage an anastomotic stricture. Neoadjuvant radiotherapy is also a strong risk factor for requiring a permanent stomas due to treatment failure.

Young Il Kim and Seung Wook Hong have equally contributed to this study as first authors.

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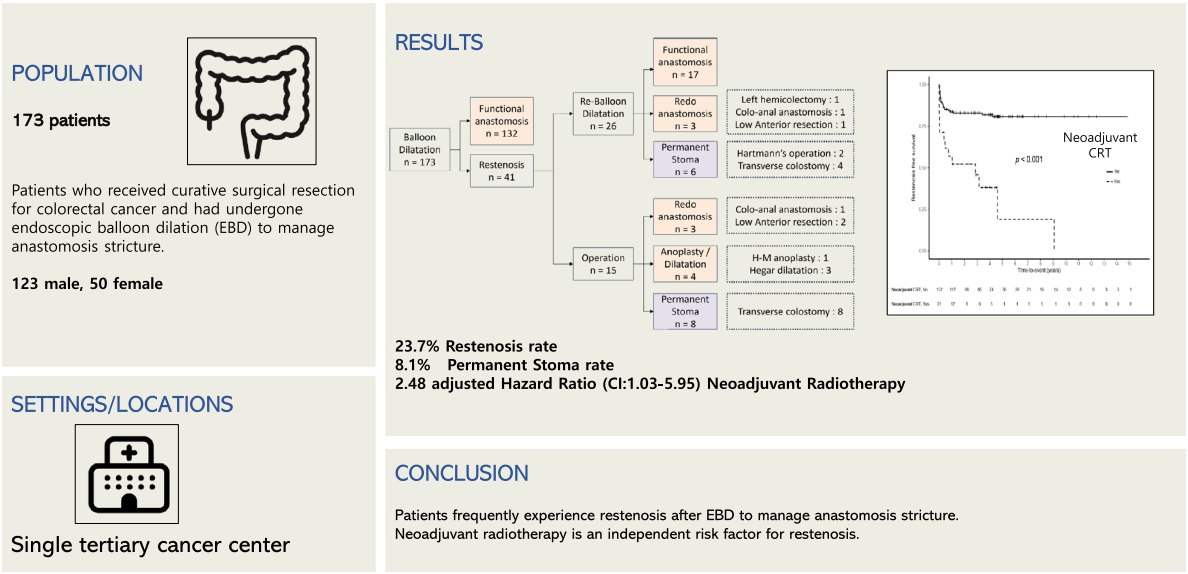
Graphical abstract



Keywords Colorectal neoplasm · Endoscopic balloon dilation · Anastomosis · Stricture

Advances in colorectal surgical techniques have increased the probability of achieving a functioning anus even in low rectal cancer cases [1–3]. Treatment choices for colorectal cancer have been developing for over a century beginning with Sir Ernest Mile's abdominoperineal resection or Hartmann's procedure to current day low anterior and intersphincteric resection techniques with coloanal anastomosis [4]. More colorectal cancer patients are now candidates for resection and anastomosis with a reduced risk of eventually requiring a permanent stoma. Notable advances in adjuvant treatments such as radiotherapy, chemotherapy, and immunotherapy also provide a higher chance of preserving the sphincter [5, 6].

Complications associated with anastomoses in colorectal surgery can be extremely serious, leading to severe morbidity and even death, and are therefore a considerable concern for both surgeons and patients [7, 8]. Leakage and stricture are the two pillars of major anastomotic complications and can occur independently or in tandem. Anastomosis stricture is reported to occur in up to 30% of colorectal surgical patients, although various studies have presented contradictory findings for the causes and risk factors for these events [9–11]. Anastomosis methodologies (stapled, hand-sewn, end-to-end, end-to-side, side-to-side), the location of an anastomosis, perioperative adjuvant treatments such as radiotherapy and chemotherapy, underlying diseases, and other factors have been sporadically reported by different studies.

While resection of the stricture site and re-anastomosis can be considered, it has been reported that such operations are demanding and complicated with a high rate of adverse events [12, 13]. Endoscopic techniques such as an endoscopic balloon dilation (EBD) has been described by many studies as effective and minimally invasive procedures [14, 15]. The complication rates of EBD are known to be low and manageable when this approach is undertaken cautiously. Hence, anastomotic strictures on presentation are primarily managed using an endoscopic procedure and thereafter by surgery if necessary. However, although EBD has proven to be an effective therapy, the treated patients frequently require follow-up procedures or additional surgical interventions, even after a successful EBD.

Few studies to date have reported on the long-term outcomes of an EBD after colorectal surgery and have only done so in a small number of cases. Hence, we here assessed the long-term outcomes of an EBD for anastomotic stricture after a colorectal cancer surgery. Risk factors for recurring strictures were analyzed.

Materials and methods

Data collection and study design

Our institutional medical records from the electronic database at a tertiary medical center (Asan Medical Center) were retrospectively searched for colorectal cancer patients treated between January 2000 and December 2022. Patients who received curative resection and anastomosis for colorectal

cancer and sequentially received EBD to treat an anastomotic stricture were included in the study cohort (Fig. 1). Patients that underwent colorectal surgeries for benign disorders such as diverticulum associated disease, ischemic colitis, trauma, and complications related to endoscopic procedures were excluded. Information regarding clinicopathological characteristics, perioperative information during the primary operation, recurrence of stenosis, and treatments were retrieved. A treatment failure was classified as either restenosis or the necessity for a permanent stoma. Patients who required a permanent stoma due to a cancer recurrence, ischemic colitis, or for reasons other than an anastomotic stricture were also not included in the study cohort.

The current study protocol was approved by the relevant institutional review board (IRB No. 2023-0423) and is reported according to the guidelines presented in the strengthening the reporting of cohort studies in surgery (STROCSS) criteria [16]. The requirement for patient informed consent was waived by the IRB due to the retrospective nature of the analysis.

Endoscopic procedure and anastomotic stricture

Anastomotic stricture was first suspected and investigated when the patients had any symptoms related to obstruction (dyspepsia, abdominal distention/pain, difficulty in defecation etc.), or of obstructive patterns were evident from a colon enema study using contrasts (Gastrografin) prior to restoration with diverting stomas. A definitive diagnosis of anastomotic stricture was confirmed by endoscopy when a conventional scope (distal end outer diameter 13.2 mm) was unable to pass the stricture site. Anastomotic stenoses were thus detected based on clinical indications or during regular endoscopic monitoring (e.g., before a planned ostomy reversal or during oncologic follow-up). All interventions to correct these strictures were performed by an endoscopist who had performed a minimum of 50 EBD procedures.

Patients underwent a bowel preparation or enema as clinically indicated. Once the endoscope reached the stricture site, a contrast agent was injected through its working channel to visualize the length of the stenosis. Subsequently, a

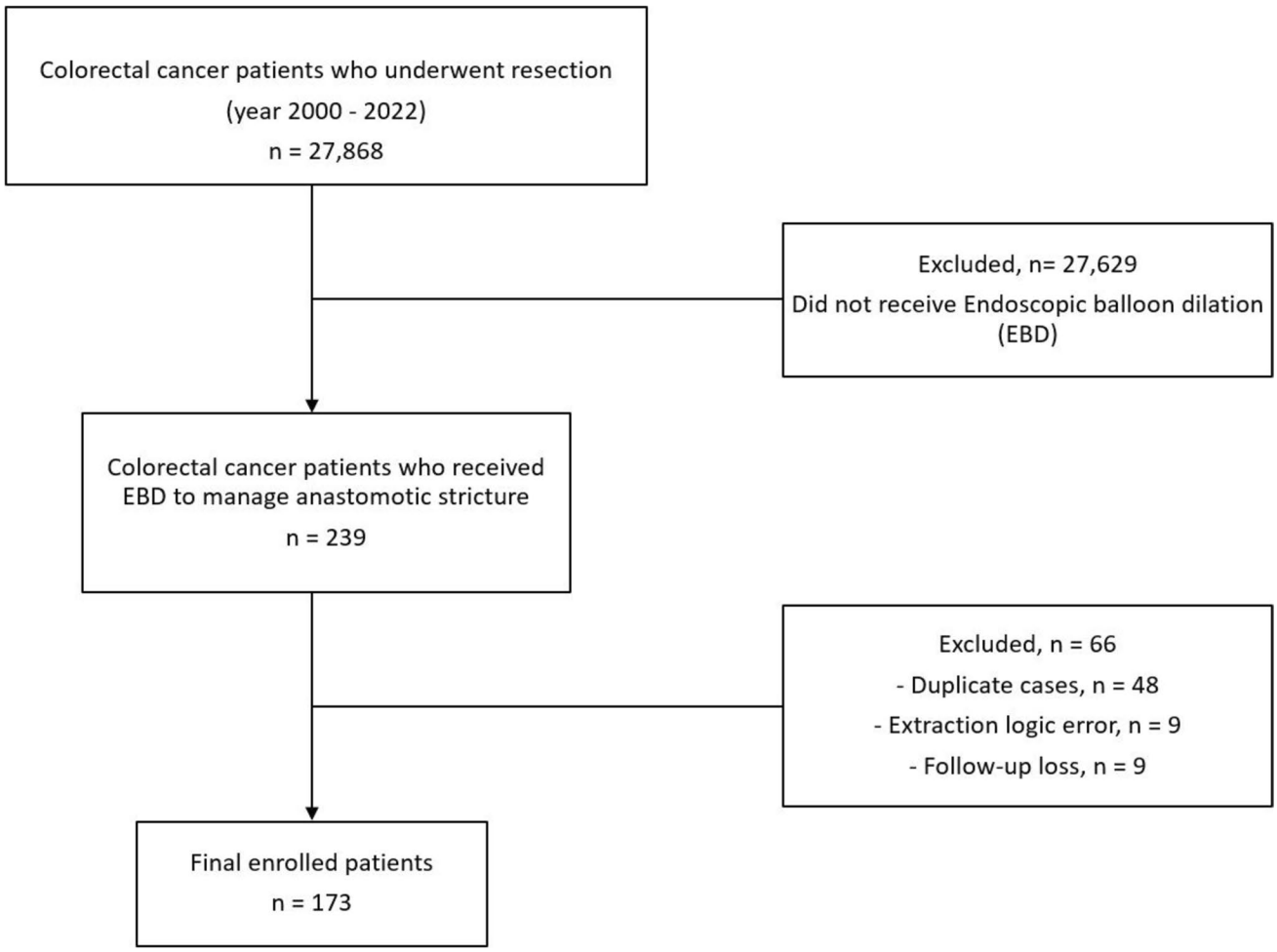


Fig. 1 Consort flow diagram of selected patients

guidewire was passed through the stenotic segment. Based on the endoscopist's subsequent assessment, the diameter and pressure for the balloon were determined. Following this, the balloon was inflated to expand the anastomotic stricture under fluoroscopic guidance.

Statistical analysis

Categorical and continuous variables were compared using the chi-squared test and Student's *t*-test, respectively. Restenosis-free survival (RFS) was defined as the time interval from the first EBD and first documented recurrence of anastomotic stricture. RFS was analyzed using the Kaplan–Meier method and the values were compared by log-rank test. Multivariable analysis was used to identify independent risk factors associated with recurrence. Variables with a P value < 0.1 in the univariable analysis were included in the subsequent multivariable analysis. All of the tests were two-sided with $P < 0.05$ considered statistically significant. All statistical analyses were performed using R software (version 4.0.2; R Foundation for Statistical Computing, Vienna, Austria).

Results

Clinicopathological characteristics of the colorectal cancer study patients

A total of 173 colorectal cancer patients matched the inclusion criteria for this present study. The mean age of the study group was 59.6 ± 12.1 years, and it comprised 123 (71.7%) male patients. The median follow-up period was 60.4 months with a standard deviation of 40.9 months. The tumor was located in the rectum in 109 (63%) cases. Eighty-three patients (48%) received a protective diverting stoma during their primary operation. A stapled anastomosis was commonly performed (90.2%) with a manual procedure only conducted for coloanal anastomoses. Neoadjuvant radiotherapy was administered for 21 patients (12.1%) and adjuvant chemotherapy for 97 patients (56.1%) (Table 1).

Among the 173 patients who received an EBD, 41 cases experienced restenosis at the EBD site (23.7%). Repeated EBD was performed in 26 cases with 17 of these patients presenting with no recurrence. A re-operation to resect the strictured site and redo the anastomosis was performed in six patients (2 coloanal anastomoses, 3 low anterior resections, 1 left hemicolectomy) with no recurrences in any of these cases. Anoplasty was performed in one patient and three further cases received a Hegar dilation with subsequent patent anastomoses. An eventual permanent stoma was required in 14 patients (8.1%). The treatment failures in these cases resulted in 2 Hartmann's procedures and 12 transverse colostomies (Fig. 2).

Table 1 Clinical characteristics of the included patients

Variables	$n = 173$
Sex, male, *n* (%)	123 (71.7)
Age at the time of surgery ± SD	59.6 ± 12.1
Underlying disease, *n* (%)	
Hypertension	63 (36.4)
DM	20 (11.5)
CAD	9 (5.2)
CVA/TIA	5 (2.9)
CKD	2 (1.2)
Location, *n* (%)	
Colon	64 (37.0)
Rectum	109 (63.0)
Operation type, *n* (%)	
Right colectomy	4 (2.3)
Left colectomy	6 (3.5)
Anterior resection	48 (27.7)
Low anterior resection	58 (33.5)
Ultra-low anterior resection	49 (28.3)
Subtotal/total colectomy	8 (4.6)
Diversion, yes, *n* (%)	83 (48.0)
Anastomosis type, *n* (%)	
Hand-sewn	17 (9.8)
Stapling	156 (90.2)
Anastomotic leak, yes, *n* (%)	10 (5.8)
Neoadjuvant radiotherapy, yes, *n* (%)	21 (12.1)
Adjuvant chemotherapy, yes *n* (%)	97 (56.1)

CAD coronary artery disease, *CVA/TIA* cerebrovascular accident/transient ischemic attack, *CKD* chronic kidney disease, *DM* diabetes mellitus, *HTN* hypertension, *SD* standard deviation

Three patients (1.7%) experienced major complications after the EBD. Anastomotic dehiscence was noted after the procedure in all three cases and a transverse loop colostomy was used as an emergency measure. Among these three patients, the stoma was reversible in one case but remained permanent in the other two patients. No other major complications were identified.

Factors associated with restenosis and the need for a permanent stoma

The restenosis group (41 patients) was significantly younger than the non-recurrent cases (55.6 years compared to 60.8 years, respectively, $P = 0.026$). In addition, more patients in the restenosis group had an underlying cerebrovascular accident/transient ischemic attack (CVA/TIA) ($P = 0.012$). The tumor location was also more commonly rectal with a higher incidence of manual anastomosis in

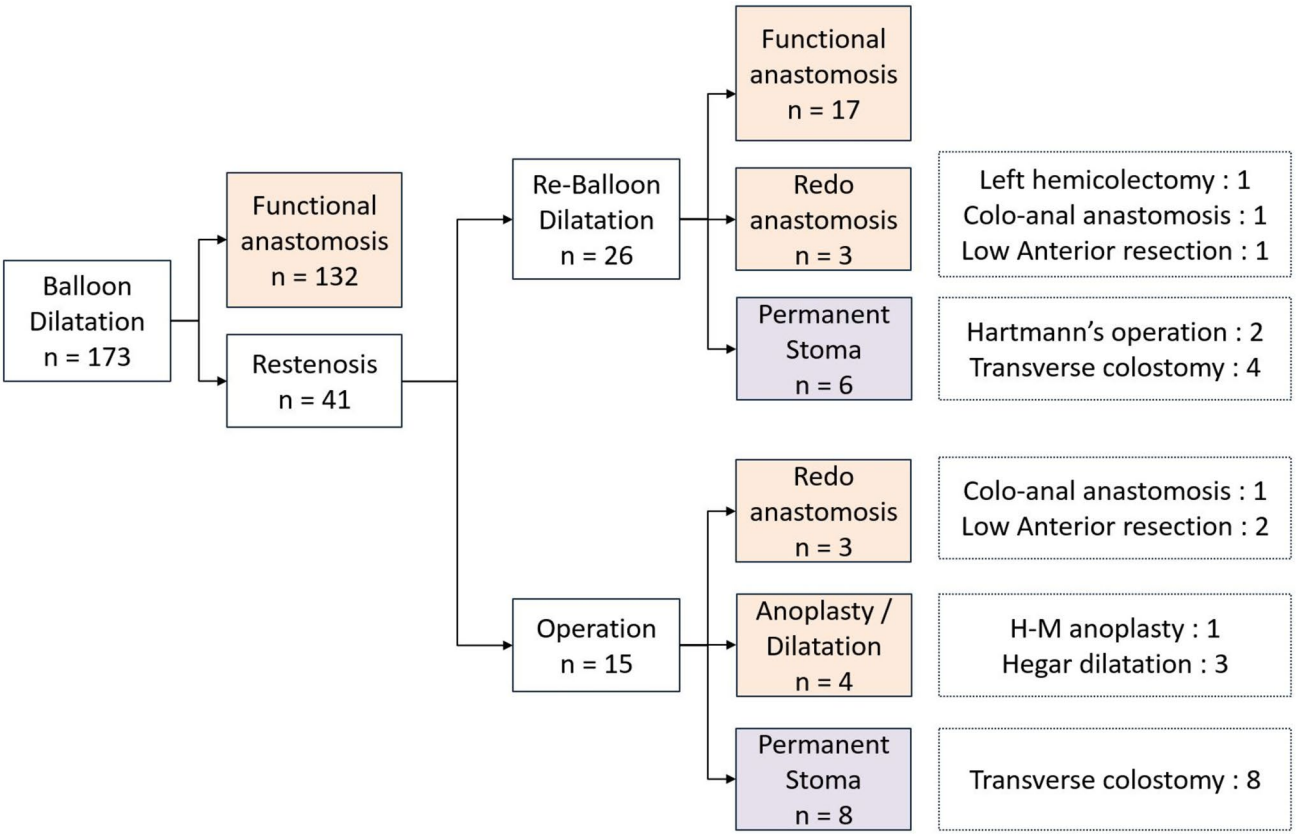


Fig. 2 Flow chart of study population

the restenosis group. Moreover, more patients received a protective diverting stoma in the restenosis group compared to the patients with no recurrence (30 patients, 73.2% versus 53 patients, 40.2%, $P < 0.001$) with a higher percentage of the recurrent patients receiving neoadjuvant radiotherapy (34.1% versus 5.3%, $P < 0.001$). Adjuvant chemotherapy was also more frequently administered in the restenosis group (Table 2).

The 1-, 3-, and 5-year RFS was 80.5%, 78.4%, and 73.9% for the study population, respectively. The median time to recurrence was 49 [37–150] days. Kaplan Meier analyses revealed a significantly poorer RFS in patients who received neoadjuvant radiotherapy (Fig. 3). After adjusting for confounding factors, neoadjuvant radiotherapy (adjusted HR 2.48, $P = 0.042$) and a history of CVA/TIA were identified as independent risk factors for restenosis (Table 3).

When comparing the patients requiring a permanent stoma to those with a functional anastomosis, all of the permanent stoma cases were found to be male (14 patients, 100%, $P = 0.011$), have a more frequent rectal tumor location, have a higher frequency of manual anastomosis, and have more commonly received neoadjuvant radiotherapy and adjuvant chemotherapy (Table 4).

Discussion

Our present study analyzed the effectiveness of EBD in the treatment of anastomotic strictures arising after colorectal surgery and identified risk factors for restenosis in a relatively large cohort of patients. Our study findings suggest that preoperative radiotherapy is a strong risk factor for recurrence of a stenosis after EBD for the treatment of an anastomotic stricture. Although EBD was found to be effective for the majority of patients in a single procedure session, approximately 20% experienced restenosis, mostly within one year of the first EBD session. While a previous study related to recurrent stenosis has suggested that repeated EBD is feasible, only 17 patients (41.5%) from the restenosis group in the present study cohort were successfully managed in this way. Other recurrent patients required redo-anastomosis, anoplasty, or an eventual permanent stoma in some cases.

Anastomotic stricture after colorectal surgery is reported to occur in up to 30% of patients [9, 10, 15]. Endoscopic treatment is recommended as a first line intervention due to its minimal invasiveness, ready access, and favorable efficacy [17]. The treatment success rate is known to be favorable with this approach, but repeated procedures are

Table 2 Comparison of clinical characteristics according to the occurrence of restenosis

Variables	No restenosis ($n=132$)	Restenosis ($n=41$)	P value
Sex, male, *n* (%)	91 (68.9)	32 (78.0)	0.354
Age at the time of surgery ± SD	60.8 ± 11.7	55.6 ± 12.9	0.026
Underlying disease, *n* (%)			
Hypertension	43 (32.6)	20 (48.8)	0.090
DM	12 (9.1)	8 (19.5)	0.091
CAD	7 (5.3)	2 (4.9)	1.000
CVA/TIA	1 (0.8)	4 (9.8)	0.012
CKD	1 (0.8)	1 (2.4)	0.419
Location, *n* (%)			0.027
Colon	56 (42.4)	8 (19.5)	
Rectum	76 (57.6)	33 (80.5)	
Diversion, yes, *n* (%)	53 (40.2)	30 (73.2)	< 0.001
Anastomosis type, *n* (%)			0.001
Hand-sewn	7 (5.3)	10 (24.4)	
Stapling	25 (94.7)	31 (75.6)	
Anastomotic leak, yes, *n* (%)	8 (6.1)	2 (4.9)	1.000
Neoadjuvant radiotherapy, yes, *n* (%)	7 (5.3)	14 (34.1)	< 0.001
Adjuvant chemotherapy, yes *n* (%)	67 (50.8)	30 (73.2)	0.019

CAD coronary artery disease, *CVA/TIA* cerebrovascular accident/transient ischemic attack, *CKD* chronic kidney disease, *DM* diabetes mellitus, *HTN* hypertension, *SD* standard deviation

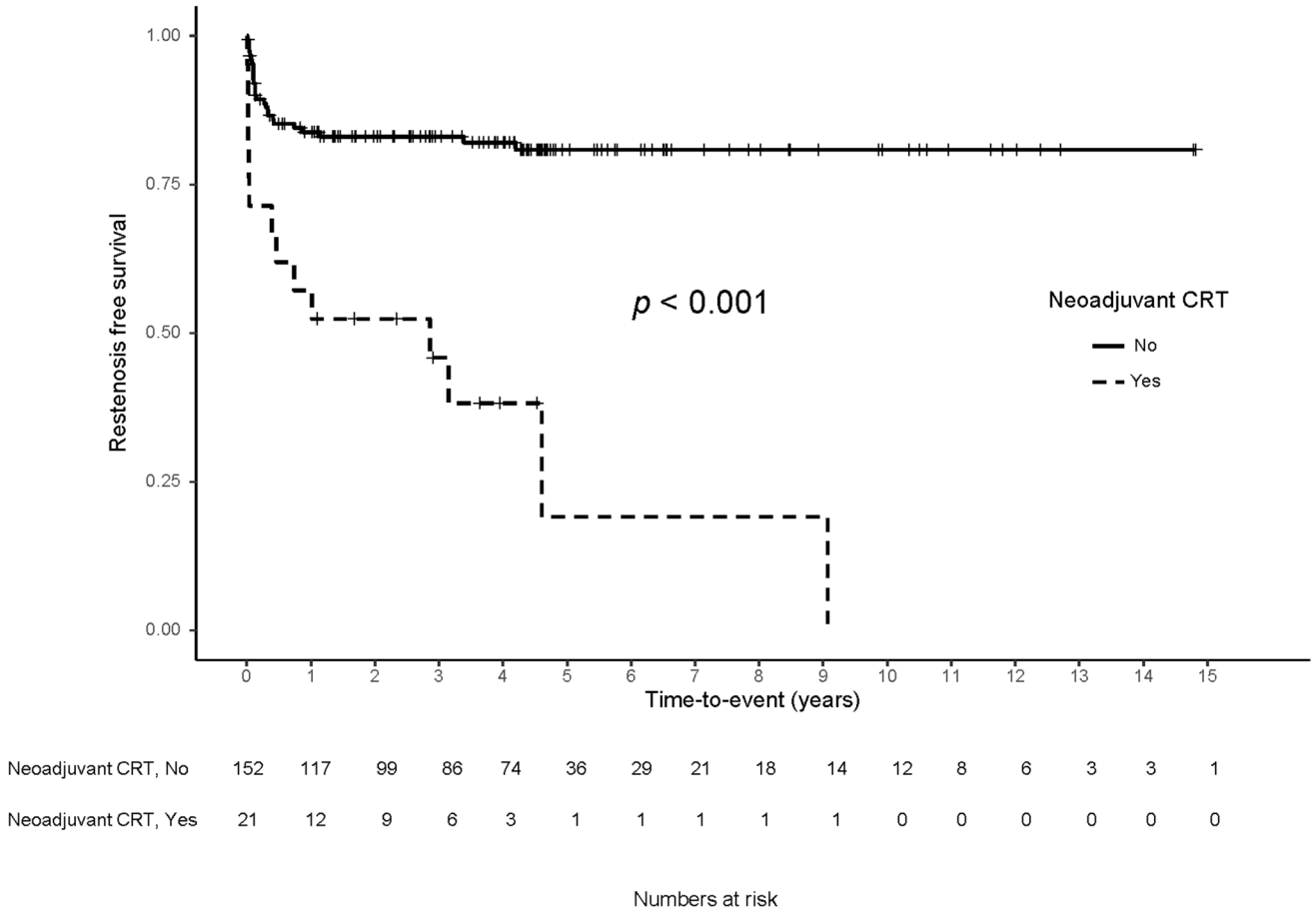


Fig. 3 Kaplan Meier analyses of restonosis free survival in patients according to neoadjuvant chemoradiotherapy

Table 3 Risk factors for restenosis onset following balloon dilatation

Variables	Crude HR (95% CI)	*P* value	Adjusted HR (95% CI)	*P* value
Age, ≥ 70 years	1.98 (0.78, 5.04)	0.154	1.6 (0.6, 4.27)	0.351
HTN	1.78 (0.97, 3.29)	0.064	1.4 (0.68, 2.86)	0.359
DM	2.19 (1.01, 4.77)	0.047	1.76 (0.76, 4.04)	0.185
CVA/TIA	6.36 (2.23, 18.11)	< 0.001	6.97 (2.15, 22.54)	0.001
Location (rectum)	2.84 (1.31, 6.16)	0.008	1.19 (0.41, 3.49)	0.747
Neoadjuvant radiotherapy	5.03 (2.63, 9.63)	< 0.001	2.48 (1.03, 5.95)	0.042
Adjuvant chemotherapy	2.36 (1.18, 4.7)	0.015	1.61 (0.73, 3.57)	0.239
Diversion	3.84 (1.91, 7.73)	< 0.001	2.42 (0.91, 6.43)	0.078
Anastomosis, hand-sewn	Reference		Reference	
Stapling	0.28 (0.13, 0.56)	< 0.001	0.81 (0.34, 1.94)	0.634

CVA/TIA cerebrovascular accident/transient ischemic attack, *DM* diabetes mellitus, *HTN* hypertension

frequently needed (up to 88%) with rare cases of serious complications known to arise after EBD [14, 15, 18–26]. The more intuitive adverse event from this procedure would be a perforation after the balloon dilation, which occurred in three out of the 173 patients (1.7%) in the present study cohort. While some studies have reported no complications from an EBD, those prior reports typically included a small number of patients, and the complication rates could therefore have been underestimated. Although the incidence rate is low, interventionists must be aware of such consequences during the EBD procedure.

Due to the low EBD case numbers, few studies to date have reported on the long-term outcomes of an endoscopic dilation. The recurrence rates have been described to range from zero to as high as 80%. A recent publication by Biraima et al. that assessed 76 patients who received EBD for anastomotic stenosis reported 11%, 22%, and 25% recurrence rates at 1, 3, and 5 years, respectively. [9] Two recurred cases in that study required an operation but 97.4% of the recurrences were treated successfully with repeated EBD. The observed recurrence rate in our present study was similar (41 patients; 23.7%). However, only 17 of our patients who experienced restenosis could be successfully treated with repeated EBD. Re-operations such as redo-anastomosis and anoplasty were performed in 18 of our current study patients (43.9%) and 14 of these cases eventually required a permanent stoma. This discrepancy may be due to the different characteristic of the patients included in the two studies. Where 56 patients (73.6%) of the cases enrolled in the Biraima study were colon resections and only 16 were (21%) rectal resections, our current cohort included 115 rectal resections (66.5%). This distinction could have influenced the EBD success rates of the two studies.

An interesting finding from our present analyses was that preoperative radiotherapy was a major risk factor for restenosis development, and this association was significant even in patients with permanent stomas. Radiotherapy at the rectum is associated with diverse complications among which anastomotic stricture has been suggested to be related to prior radiation [27]. At the start of radiotherapy, an acute inflammatory reaction occurs in the affected bowel mucosa. This response advances to vascular changes which can lead to chronic inflammation and fibrotic tissues. This phenomenon is an ongoing process as the intimal fibrosis of the arterioles increase with time after radiotherapy [28, 29]. Considering these effects of radiation on the rectal mucosa, the outcome of colorectal anastomosis can be compromised directly or even after a substantial amount of time has passed. In view of the aforementioned adverse effects of radiation, patients should be strictly selected for radiotherapy in the pelvis. Although neoadjuvant chemoradiotherapy has been the treatment of choice for more than a decade in such cases, a recent notable study has presented non-inferior

Table 4 Comparison of clinical characteristics between patients with a functional anastomosis or a permanent stoma

Variables	Functional anastomosis ($n=159$)	Permanent stoma ($n=14$)	P value
Sex, male, *n* (%)	109 (68.6)	14 (100.0)	0.011
Age at the time of surgery	59.7 ± 11.9	57.6 ± 15.3	0.625
Underlying disease, *n* (%)			
Hypertension	56 (35.2)	7 (50.0)	0.417
DM	16 (10.1)	4 (25.0)	0.095
CAD	9 (5.7)	0	1.000
CVA/TIA	5 (3.1)	0	1.000
CKD	2 (1.3)	0	1.000
Location, *n* (%)			0.041
Colon	62 (39.0)	2 (7.1)	
Rectum	97 (61.0)	12 (85.7)	
Diversion, yes, *n* (%)	86 (54.1)	4 (28.6)	0.120
Anastomosis type, *n* (%)			0.035
Hand-sewn	13 (8.2)	4 (28.6)	
Stapling	146 (91.8)	10 (71.4)	
Anastomotic leak, yes, *n* (%)	10 (6.3)	0	1.000
Neoadjuvant radiotherapy, yes, *n* (%)	12 (7.5)	9 (64.3)	< 0.001
Adjuvant chemotherapy, yes *n* (%)	85 (53.5)	12 (85.7)	0.040

CAD coronary artery disease, *CVA/TIA* cerebrovascular accident/transient ischemic attack, *CKD* chronic kidney disease, *DM* diabetes mellitus, *HTN* hypertension

disease-free survival outcomes in patients treated with preoperative chemotherapy alone compared with conventional preoperative chemoradiotherapy (PROSPECT trial) [30]. In addition, a PD-1 blockade has shown remarkable effects in highly selected rectal cancer patients in whom radiotherapy has been omitted [31]. These new treatment options for rectal cancer could thus spare more patients from the need for radiotherapy.

Our present study was limited by its retrospective study design. The anastomotic stricture incidence rate could not be assessed as patients were only screened for an EBD procedure. Patients who received upfront surgery for anastomotic stricture either electively or due to emergent reasons could not be evaluated. Also, patients were treated by different surgeons and endoscopists during the extensive study period of 23 years. However, our present findings clearly indicate the deteriorating effects of radiotherapy when treating an anastomotic stricture with EBD. The seemingly high rate of a permanent stoma (8.1%) in our present cohort compared to other studies of EBD is not so discouraging when compared to an investigation that was limited to low rectal cancer cases and reported that 32.6% of these patients required a permanent stoma due to anastomotic stricture [27]. Our current study also included a higher percentage of rectal cancer cases compared to other studies reporting better outcomes of an EBD [9, 32]. Also, the patients in our present cohort who eventually received a permanent stoma were all male cases with a very low anastomosis level (< anal verge 5 cm), which hinders the chances that the anastomosis can be redone. The rather low neoadjuvant radiotherapy rate among the rectum resection patients (19.6%) is mainly due to the period in which patients were recruited. During the early 2000s, neoadjuvant CRT rate was approximately 18.5% in our institute. [33]

In conclusion, EBD is an effective intervention for treating an anastomotic stricture after colorectal surgery, but recurrences are frequent. Preoperative radiotherapy is a significant risk factor for EBD failure. A repeat anastomosis can be an alternative effective treatment in such instances although it is difficult to perform in low rectal cancers.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00464-023-10661-2.

Funding This study was supported by the National R&D Program for Cancer Control through the National Cancer Center (NCC) funded by the Ministry of Health & Welfare, Republic of Korea (HA22C0042).

Declarations

Disclosures Dr. Young Il Kim, Seung Wook Hong, Seok-Byung Lim, Dong-Hoon Yang, Eon Bin Kim, Min Hyun Kim, Chan Wook Kim, Jong Lyul Lee, Yong Sik Yoon, In Ja Park, and Chang Sik Yu have no conflicts of interest or financial ties to disclose.

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