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Endoscopic balloon dilation of colorectal strictures complicating Crohn's disease: a multicenter study

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Abbreviations: Crohn's disease, CD ; EBD, endoscopic balloon dilation ; UC, ulcerative colitis ; IBD, inflammatory bowel disease.

Competing interest:

- Mélanie Serrero : Janssen, Celltrion, Pfizer, Abbvie, Takeda, MSD, Amgen, Ferring, Tillots
 - Guillaume Bouguen received lecture fees from Abbvie, Ferring, MSD, Takeda and Pfizer and consultant fees from Takeda, Janssen
 - Benjamin Pariente received consulting fees from AbbVie, MSD, Takeda, Janssen, Lilly, Pfizer, Biogaran, Mylan, Sandoz; and lecture fees: Abbvie, MSD, Takeda, Janssen, Mylan, Sandoz, Ferring
 - Romain Altwegg has received lecture and consulting fees from Abbvie, MSD, Pfizer, Takeda and Janssen
 - Jérôme Filippi has received lectures and consulting fees from Abbvie, Amgen, Biogen, Celltrion, Janssen, MSD, Pfizer, Takeda
 - Anthony Buisson: lecture fees for Abbvie, Amgen, Biogen, Ferring, Janssen-Cilag, Mayoli-Spindler, MSD, Pfizer, Roche, Takeda and Tillotts, Vifor Pharma and consulting fees for Abbvie, Amgen, Biogen, Celltrion, Janssen-Cilag, Mylan, Pfizer, Roche, Takeda and Tillotts.
 - David Laharie received counseling, boards or transports fees from Abbvie, Biogaran, Biogen, Ferring, HAC-pharma, Janssen, MSD, Novartis, Pfizer, Prometheus, Roche, Takeda, Theradiag, Tillots.
 - Maria Nachury has received lecture and consulting fees from Abbvie, Adacyte, Amgen, Biogen, MSD, Boehringer, Pfizer, Takeda, Janssen, and Ferring.
 - Lucile Boivineau lecture and consulting fees from Abbvie and Tillotts.
 - Guillaume Savoye has received lecture fees from Vifor Pharma, Takeda, Pfizer, HAC Pharma, Abbvie, MSD, and Ferring France. This author has also received travel accommodations from Ferring, Abbvie, and MSD France as well as a research grant from Ferring.
 - Lucine Vuitton has received lecture or consulting fees from Abbvie, Amgen, Janssen, Pfizer, Ferring, Mayoli, Takeda, Gilead, MSD, Life partners.
 - Laurent Peyrin-Birouley has received personal fees from AbbVie, Janssen, Genentech, Ferring, Tillots, Pharmacosmos, Celltrion, Takeda, Boehringer Ingelheim, Pfizer, Index Pharmaceuticals, Sandoz, Celgene, Biogen, Samsung Bioepis, Alma, Sterna, Nestle, Enterome, Allergan, MSD, Roche, Arena, Gilead, Hikma, Amgen, BMS, Vifor, Norgine; Mylan, Lilly, Fresenius, Oppilan Pharma, Sublimity Therapeutics, Applied Molecular Transport, OSE Immunotherapeutics, Entera, as well as grants from Abbvie, MSD, Takeda. Stock options: CTMA.
 - Mathurin Fumery has received lecture and consulting fees from Abbvie, MSD, Boehringer, Pfizer, Celltrion, Takeda, Celgene, Gilead, Janssen, and Ferring.
- No conflicts of interest are claimed by the remaining authors.

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Ethical statement : The protocol was approved by the Amiens University Hospital Ethics Institutional Reviews Board committee according to French guidelines (PI2019-843-0033).

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Generation, Collection, Assembly, Analysis and/or Interpretation of data: MT, MF, MD
Drafting or revision of the manuscript: MS, FP, GB·BP, RA·PB, JF, PV, AB, AD DL, ELB, MN, LB·GS, XH·LP, CY, FB, LV, LPB, MF
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Abstract

Introduction: While endoscopic balloon dilation (EBD) is widely used to manage ileal strictures, EBD of colorectal strictures remains poorly investigated in Crohn's disease (CD).

Methods: We performed a retrospective study that included all consecutive CD patients who underwent EBD for native or anastomotic colorectal strictures in 9 tertiary centers between 1999 and 2018. Factors associated with EBD failure were also investigated by logistic regression.

Results: Fifty-seven patients (25 women, median age: 36 years (InterQuartile Range, 31-48) were included. Among the 60 strictures, 52 (87%) were native, 39 (65%) measured < 5 cm and the most frequent location was the left colon (27%). Fifty-seven (95%) were non-passable by the scope and 35 (58%) were ulcerated. Among the 161 EBDs performed (median number of dilations per stricture: 2, IQR 1-3), technical and clinical success were achieved for 79% (n=116/147) and 77% (n = 88/115), respectively. One perforation occurred (0.6% per EDB and 2% per patient). After a median follow-up of 4.3 years (IQR 2.0-8.4), 24 patients (42%) underwent colonic resection and 24 (42%) were asymptomatic without surgery. One colon lymphoma and one colorectal cancer were diagnosed (3.5% of patients) from endoscopic biopsies and at the time of surgery, respectively. No factor was associated with technical or clinical success.

Conclusion: EDB of CD-associated colorectal strictures is feasible, efficient and safe, with more than 40% becoming asymptomatic without surgery.

INTRODUCTION

Crohn's disease (CD) is a chronic progressive and destructive conditions (1). Colorectal strictures are observed in 8 to 14% of patients with CD (2-6). The natural evolution of these strictures is poorly understood. In addition to the obstructive symptoms observed in most patients, the occurrence of colonic strictures raises concerns about the risk of malignant complications. The risk of dysplasia or cancer associated with colorectal strictures varies among studies and ranges from 0.5 to 7% in CD (2-4). Diagnosing neoplastic lesions from endoscopic biopsies is challenging in clinical practice and their absence in endoscopic biopsies cannot formally rule out the presence of dysplasia/cancer (5). Furthermore, non-passable strictures limit the endoscopic monitoring of disease activity and the surveillance of dysplasia of the upper colon. Endoscopic balloon dilation (EBD) has become a standard of care for small bowel strictures (6). The recent ECCO-ESCP guidelines recommend EBD for the management of colonic strictures in CD (7). However, the level of these recommendations is very low, as no dedicated study has specifically evaluated the effectiveness and safety of EBD in colonic strictures. Most data on EBD come from small-bowel strictures or pooled analysis. Adujar et al. compared the effectiveness of EBD of 49 colonic strictures complicating inflammatory bowel diseases with those of ileal strictures. After a median follow-up of 40 months, 30% of the patients with colonic stricture required a surgery or the placement of a stent (8). A study by the Ann Arbor group reported similar results in 46 patients with colonic strictures complicating CD, with 34% of surgery after a median of follow-up of 40 months (9). We therefore aimed to evaluate the effectiveness and safety of EBD for colonic strictures in patients with CD in a multicenter retrospective study.

MATERIALS AND METHODS

Study population

Nine French academic centers with a database including all consecutive IBD patients who underwent EBD were selected. Inclusion criteria were patients: (i) with CD diagnosis according to ECCO guidelines (12), (ii) being ≥ 18 years of age, and (iii) having had at least one EBD for native or anastomotic rectal or colonic stricture between 1999 and 2018.

Data collection

Clinical, endoscopic, surgical, and pathological data were retrospectively extracted from patient hospital medical records using a standardized questionnaire that was developed specifically for this study. The following clinical data were collected: age, sex, date of IBD diagnosis, disease location, age at diagnosis and at the time of dilation, previous and current treatments, and previous surgery. The following information concerning strictures were collected: symptomatic character, location, number, type (native or anastomotic), duration, length, presence of ulcerations on the stricture and/or colon, passable (or not) with the endoscope, and histological results of biopsies. The collected EBD data were the number of procedures, balloon diameter, passable or not after the procedure, clinical efficacy, associated complications and modifications in IBD therapy at the time of dilation. The collected data during follow-up until last news were colonic resection and diagnosis of dysplasia or cancer.

Definitions and outcomes

Stricture was defined according to the ECCO definition as a fixed, localized and persistent colonic narrowing (9). Endoscopic failure was defined by the need for

surgical colonic resection or the persistence of obstructive symptoms at the end of follow-up. Technical efficacy was defined by a passable stricture after the EBD, clinical efficacy as an improvement of obstructive symptoms after dilation according to physician judgement. All major complications related to the procedure requiring hospitalization, transfusion, urgent endoscopic or surgical intervention were recorded for safety assessment.

Statistical Analysis

Categorical variables are expressed as percentages. Continuous variables are reported as the median with interquartile range [IQR]. The distribution of the time to surgery from the 1st dilation was estimated using the non-parametric method of Kaplan-Meier. Factors related to surgery were assessed using a univariate survival model (Cox) by calculating a Hazard-Ratio (HR) with a 95% confidence interval. For the multivariate Cox model, a backward selection method was used. All data analysis was performed using SAS® version 9.4 software (SAS Institute, Cary, NC). Survival curves were constructed using R 3.2.3 software. The protocol was approved by the Amiens University Hospital Ethics Institutional Reviews Board committee according to French guidelines (PI2019-843-0033).

RESULTS

Study population

We identified 57 patients who underwent 161 EBD procedures for 60 colorectal strictures between 1998 and 2018. The main characteristics of the population are presented in **Table 1**. About half of patients (52%) had ileocolonic location. Twenty-five patients (44%) were female and the median age at EBD was 36 years (IQR, 31-48). Twenty-two (39%) patients had at least one intestinal resection prior to EBD, including 9 (15%) with segmental colonic resection. At the time of dilation, 73% had been previously exposed to thiopurines, 70% to anti-TNF treatment, 7% to vedolizumab, and 5% to ustekinumab therapy.

Stricture characteristics

The stricture characteristics are presented in **Table 1**. The median time between CD diagnosis and stricture diagnosis was three years (IQR, 5 – 20). Thirteen (23%) patients had more than one stricture and 42 (74%) had stricture-related symptoms. Fifty-two (87%) strictures were native and the most common location was the left colon (28%). Most strictures (n = 39, 65%) were short (< 5 cm) and 35 (59%) were ulcerated. Only three strictures (5%) were passable before dilation. Biopsies were performed on 37 strictures (68%) and only one (2.7%) of them was malignant at the time of dilation, with a diagnosis of lymphoma (biopsies performed during the same procedure).

Endoscopic balloon dilation

A median of two dilations (IQR, 1-3) was performed per patient with 30 patients who had only one dilatation. At stricture dilation, 35 (53%) had biological signs of inflammation, as defined by CRP > 5 mg/L and/or calprotectin > 250 µg/g, and 44

(77%) had endoscopic ulcerations. CD medical therapy was changed for 22% (n = 36/161) of cases after dilation.

Short and long-term effectiveness

Technical efficacy was achieved for 116 of 147 dilations performed (79%) in patients with non-passable strictures. In patients with stricture-related symptoms, clinical efficacy was observed for 77% of dilations (n = 88/115). After a median of follow-up of 4.3 years [2.0 ; 8.4], 24 patients (42%) underwent a colonic resection for stricture and 24 (42%) were asymptomatic without surgery. The cumulative risk of colonic resection at one, three and five years were 19% [9; 30], 34% [21; 47], and 47% [32; 62], respectively (**Figure 1**). Outcomes at the end of follow-up are presented in **Figure 2**. Nine patients (16%) had a non-passable and symptomatic stricture, 11 (19%) a non-passable but asymptomatic stricture, 8 (14%) a passable stricture and 5 (9%) had no stricture, without surgery. One colorectal cancer was diagnosed in one of 57 patients (1.7%). The diagnosis was made on the operative specimen after segmental colonic resection. Three patients (5.3%) underwent hospitalization for stricture-related obstructive symptoms. In univariate analysis, disease duration (HR, 0.99; CI95% [0.98; 0.99], p= 0.005), strictures length (HR, 2.68; CI95% [0.88; 8.16], p= 0.083), and number of dilation (HR, 0.76; CI95% [0.58; 1.01], p= 0.057) were associated with surgery. In multivariate analysis, only disease duration remains significantly associated with surgery (HR, 0.99; CI95% [0.98; 0.99], p= 0.005) (**Table 2**).

Safety

Of the 161 dilations performed, only one perforation occurred (complication rate of 0.6% per procedure, 2% per patient). No other complication during follow-up was reported.

DISCUSSION

Colorectal strictures in CD are frequently diagnosed but their management remains a challenge in clinical practice. First, colonic strictures are associated with a high rate of obstructive symptoms. Second, they raise concerns about neoplastic complications that cannot be fully excluded by negative endoscopic biopsies (5). Third, non-passable strictures limit the endoscopic monitoring of disease activity and the surveillance of dysplasia of the upper colon. On the opposite, segmental or total colectomy are associated with a significant morbidity (7, 8, 10).

The recent ECCO-ESCP guidelines recommend EBD or segmental resection for colonic strictures in CD (7). However, these recommendations are based on a low level of evidence, because no study has specifically evaluated the effectiveness and safety of EBD in IBD colonic strictures.

Most data on EBD come from small-bowel strictures or pooled analysis. A systematic-review (11) including 24 studies and 1,163 patients with CD and EBD on small-bowel or ileo-colonic anastomotic stricture reported a technical efficacy of 90%, a clinical efficacy of 80%, and a surgical rate of 27% (6). Here, we have observed a technical success of 79% and a clinical efficacy of 77%, demonstrating that EBD of CD colonic strictures is an effective and safe procedure. After a median follow-up of 4 years, we observed that about 40% of patients with EBD of colonic strictures were asymptomatic without surgery. On the other hand, 42% of patients need colonic resection. There are several possible explanations for the relatively frequent resort to

surgery in our study. The only goal of EBD in the treatment of small-bowel strictures is to improve obstructive symptoms, whereas dilation of colonic strictures must also allow exploration of the entire stricture and make it possible to cross it to properly, in order to examine the colon upstream. The technical success rate, which may be slightly lower for colonic strictures, was 79% in our study *versus* 83 to 100% for small-bowel strictures (6,11-13). This may also be related to a smaller number of anastomotic strictures in our study. In addition, the greater fear of neoplastic complications in patients with colonic stricture (in comparison with those with small-bowel stricture) results in a lower threshold for surgery in this situation. However, reported data show that high-grade dysplasia or colorectal cancer is observed in 1.2% of patients with CD and 7% of patients with UC, even if endoscopic biopsies are negative (5). The non-passable character of the stricture and the inability to properly explore it and detect dysplasia or CRC in the upstream colon are factors that may influence clinicians to perform surgery. Ultimately, these factors make it difficult to compare our rate of surgery with the data available on small-bowel strictures. Of note, no dilation was proposed to UC patients during the study period. The greater fear of a neoplastic complication in this population probably explains systematic colonic resection.

The major concern for EBD is the risk of perforation. The complication rate, based on available data, varies between 0 and 4% (6,11-13). Only one study reported a higher rate, with 10.3% perforation, occurring exclusively for colonic stricture (14). In our study, we report only one (0.6%) major complication. This result is similar to the data available for ileal stricture.

Our study had several limitations, mainly linked to its retrospective design. The lack of standardization of the dilation procedure may have influenced our results. Also, the

lack of power linked to our small population limits the identification of factors associated with EBD success. In multivariate analysis, only disease duration remains significantly associated with surgery but with an HR, 0.99; CI95% [0.98; 0.99] therefore limiting the interpretation and applicability of this result. Our study also had several strengths, including the fact that patients were included consecutively from 9 different centers. This is currently the largest cohort of EBD of colonic strictures in IBD. Finally, the 52-months median follow-up period allowed us to evaluate the long-term effectiveness of EBD.

In conclusion, EBD of CD colorectal strictures is safe and effective. About 40% of patients were asymptomatic without surgery at the end of the follow-up period. These results must be confirmed by prospective studies, but they confirm the room of EDB in the algorithm for management of colonic strictures in CD.

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Tables

Table 1. Characteristics of the population. IBD: inflammatory bowel disease, IQR: interquartile range.

	N = 57
<u>Characteristics of the population</u>	
Gender , female (n, %)	25 (43,9 %)
Median age at dilation (years, IQR)	36 [31-48]
Disease location (n, %)	
Colonic, L2	26 (46%)
Ileocolonic, L3	31 (54%)
Phenotype (n, %)	
Stricturing B2	28 (49%)
Penetrating B3	29 (51%)
Previous surgery (n, %)	
Ileocecal resection	22 (38,6%)
Small bowel resection	13 (22.8%)
Colonic resection	4 (7.0%)
	9 (15.7%)
<u>At stricture dilation</u>	
Endoscopic ulceration (n, %)	44 (77.2%)
Biological inflammation (CRP > 5 mg/L or calprotectin > 250 ug/g)	30 (52.6%)
Time between IBD diagnosis and stricture diagnosis (y, IQR)	13 [5-20]
Number of strictures/patient (n, %)	
One	44 (77.2%)
Two	10 (17.5%)
Three	3 (5.2%)
Type of stricture (n, %)	
Native	52 (86.7%)
Anastomotic	8 (13.3%)
Stricture location (n, %)	
Right colon	5 (8.3%)
Transverse colon	13 (21.7%)
Left colon	16 (26.7%)
Sigmoid	13 (21.7%)
Rectum	13 (21.7%)
Ulcerated stricture (n, %)	35 (58.3%)
Non-passable stricture (n, %)	57 (95.0%)
Strictures length (n, %)	
≤ 5cm	39 (65.0%)
> 5cm	6 (10.0%)
Missing	15 (25%)
Stricture related symptoms (n, %)	42 (73.7%)
Median number of dilations per patient (n, IQR)	2 (1-3)
Median size of the thinnest balloon used (mm, IQR)	15 (12-15)
Median size of the widest balloon used (mm, IQR)	18 (16-18)
Treatment at first dilation	
5-ASA (n, %)	6 (10.5%)
Thiopurines (n, %)	16 (28.0%)
Methotrexate (n, %)	3 (5.3%)

Infliximab (n, %)	16 (28.0%)
Adalimumab (n, %)	16 (28.0%)
Vedolizumab (n, %)	2 (3.5%)
Ustekinumab (n, %)	2 (3.5%)
Others (n, %)	8 (14.0%)
Modification of IBD-related treatment at dilation (n, %)	36 (22.4%)
Immunosuppressant initiation	3 (8.3%)
Anti-TNF initiation	7 (%)
Immunosuppressant and anti TNF initiation	1 (2.8%)
Anti-TNF optimization	11 (30.5%)
Anti-TNF switch	3 (8.3%)
Vedolizumab initiation	2 (5.5%)
Others	9 (25%)

Table 2. Univariate analysis of factors associated with delay to surgical resection for colorectal stricture. HR, Hazard-Ratio ; CI, confidence interval

	Univariate analysis	Multivariate analysis
Variable	HR [CI95%], p-value	HR [CI95%], p-value
age	1.01 [0.98; 1.04] p= 0,683	
Symptomatic stricture	1.22 [0.45; 3.32] p= 0,7	
Disease activity	1.48 [0.44; 5.01] p= 0,528	
Disease duration	0.99 [0.98; 0.99] p= 0,005	0.99 [0.98; 0.99] p= 0.005
Stricture length	2.68 [0.88; 8.16] p= 0,083	
number of strictures	0.83 [0.34; 2.03] p= 0,688	
ulcerated	0.83 [0.37; 1.9] p= 0,664	
Stricture location	1.24 [0.89; 1.73] p= 0,212	
Anastomotic stricture (vs native)	0.73 [0.21; 2.48] p= 0,608	
Balloon diameter	1.04 [0.88; 1.23] p= 0,635	
Number of dilatations	0.76 [0.58; 1.01] p= 0,057	
Therapeutic modification	0.67 [0.27; 1.62] p= 0,37	

Figure 1. Probability of surgery since the first endoscopic balloon dilation

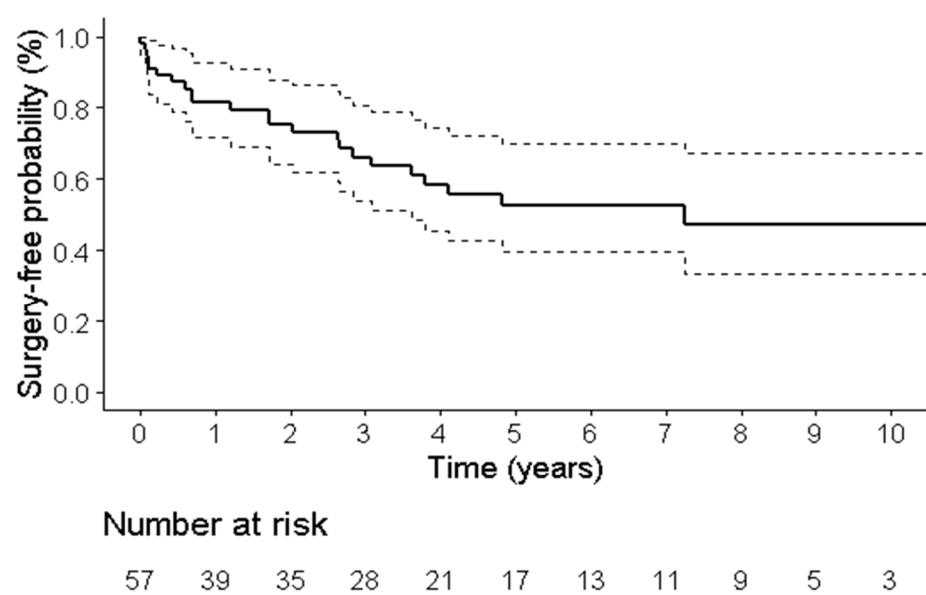


Figure 2 : . Final outcomes at the end of follow-up

