ORIGINAL ARTICLE

Clinical Efficacy of Endoscopic Treatment for Benign Colorectal Stricture: Balloon Dilatation versus Stenting

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Background/Aims: There has been a lack of research comparing balloon dilatation and self-expandable metal stent (SEMS) placement to determine which is better for long-term clinical outcomes in patients with benign colorectal strictures. We aimed to compare the clinical efficacy and complication rates of balloon dilatation and SEMS placement for benign colorectal strictures from a variety of causes. **Methods:** Between January 1999 and January 2012, a total of 43 consecutive patients who underwent endoscopic treatment for benign colorectal stricture (balloon only in 29 patients, SEMS only in seven patients, and both procedures in seven patients) were retrospectively reviewed. **Results:** Thirty-six patients underwent endoscopic balloon dilatation, representing 65 individual sessions, and 14 patients received a total of 17 SEMS placements. The initial clinical success rates were similar in both groups (balloon vs SEMS, 89.1% vs 87.5%). Although the reobstruction rates were similar in both groups (balloon vs SEMS, 54.4% vs. 57.1%), the duration of patency was significantly longer in the balloon dilatation group compared with the SEMS group (65.5±13.3 months vs. 2.0±0.6 months, p=0.031). **Conclusions:** Endoscopic balloon dilatation is safe and effective as an initial treatment for benign colorectal stricture and as an alternative treatment for recurrent strictures. **(Gut Liver 2015;9:73-79)**

Key Words: Benign stricture; Colorectal stricture; Balloon dilatation; Self-expandable metal stent

INTRODUCTION

Acute colorectal obstruction is a surgical emergency and is commonly caused by colorectal malignancies.[1-4] However, benign conditions, such as scarring from prior operations, radiation, inflammatory bowel disease, diverticulitis, and ischemia, can also lead to colorectal obstruction.[3-13] The most common cause of benign colorectal stricture is postoperative anastomotic stricture, which occurs commonly in the extraperitoneal distal rectum.[3,8-13] Traditionally, benign strictures have been treated with surgical intervention, including resection and reanastomosis.[8]

Since the first balloon dilatation for a benign rectal stricture was performed in 1984,[14] endoscopic balloon dilatation has been regarded as a first line therapy for benign colorectal stricture, especially in case of postoperative stricture or inflammatory bowel disease.[8-12,15] One previous study reported that 91.7% of patients had successful dilatation using the through-the-scope (TTS) method in 24 patients with anastomotic strictures after anterior rectal resection.[8] No procedure-related complications were reported. In the setting of Crohn's disease, a previous study showed that immediate success of a first dilatation was 97% in 237 dilatations of 138 patients.[16] During the follow-up of 5.8 years, 76% of patients were able to avoid surgical treatment. Therefore, it is widely accepted that balloon dilatation is a safe and an effective method for postoperative colorectal stricture or inflammatory bowel disease.

Although self-expandable metal stent (SEMS) placement has been accepted as an alternative therapy for malignant colorectal obstruction,[17-20] there is little evidence for the efficacy of this therapy in the treatment of benign colorectal strictures.[21] Previous work showed that the clinical efficacy of SEMS was as high

as 95% in 23 patients with left-sided benign colorectal strictures. However, the major complication rate was 38%, including 8.7% of patients who had perforations.[5] Until now, there has been a lack of evidence comparing these two endoscopic treatment options to determine which is better for long-term clinical outcomes in patients with benign colorectal strictures. We, therefore, aimed to compare the clinical efficacy and complication rates of balloon dilatation and SEMS placement for benign colorectal strictures from a variety of causes.

MATERIALS AND METHODS

1. Patients

Between January 1999 and January 2012, a total of 43 consecutive patients who underwent endoscopic treatment for benign colorectal stricture at Severance Hospital, Yonsei University College of Medicine, Seoul, Korea were included in the present study. Among these 43 patients, 29 (67.4%) underwent balloon dilatation only, seven patients (16.3%) underwent SEMS only, and seven patients (16.3%) underwent both treatments. The therapeutic modality was selected by the discretion of the endoscopists. In total, 36 patients received a total of 65 sessions of endoscopic balloon dilatation and 14 patients received a total of 17 SEMS placements.

2. Endoscopic treatment

Endoscopic treatment with balloon dilatation or SEMS placement was performed using the TTS method under fluoroscopy by expert endoscopists. A wide working channel endoscope (GIF-Q260; Olympus Optical Co., Ltd., Tokyo, Japan) was used for all exploration. Water soluble contrast material (gastrografin) was injected through the catheter to visualize and measure the length of the stricture. Then, a 7F catheter was passed endoscopically with the aid of a guidewire (Hydra-Jagwire 0.035 in×450 cm; Boston Scientific, Natick, MA, USA) and inserted through the stricture. In cases of balloon dilatation, the TTS hydrostatic balloon was inserted through the stricture with aid of fluoroscopy and was expanded for a period of 30 seconds, one to two times during a session. A 15- to 20-mm balloon was used, depending on the stricture diameter, and was filled with water to obtain adequate pressure as assessed by visualization and pressure monitoring. In cases of SEMS placement, a Comvi® covered stent (Taewoong Medical Co., Ltd., Gimpo, Korea), 20 mm in diameter and either 60, 80, 100, or 120 mm in length, a Niti-S® uncovered D-type stent (Taewoong Medical Co., Ltd.), 24 mm in diameter and 60, 80, 100, or 120 mm in length, or a Hanarostent® covered stent (M.I.Tech Co., Ltd., Seoul, Korea), 22 mm in diameter and 80 mm in length was selected based on length of stricture and used for the procedure. The length of the stent was chosen to allow for at least an additional 2 cm on each side of the obstruction to obtain adequate margins. After the deployment of the stent, its position was assessed by the endoscopists under fluoroscopic visualization. A plain X-ray was obtained to confirm the proper position and expansion of SEMS.

3. Definitions

Technical success was defined as a successful balloon dilatation or stent deployment across the stricture. Clinical success was defined as colonic decompression or relief of obstructive symptoms within 48 hours after a technically successful endoscopic treatment. Reobstruction was defined as a recurrence of obstructive symptoms during follow-up after prior achievement of clinical success. In addition, we defined procedural failure as events which made a need to perform additional endoscopic treatment or surgery. Technical failure, clinical failure, and reobstruction were included in procedural failure. In addition, duration of patency was defined as the time from the initial endoscopic treatment to the first procedural failure. Endoscopic treatment failure was defined as the condition of the patients who were not able to continue to undergo further endoscopic treatment despite indications for further therapy, or underwent surgical treatment including ileostomy or colostomy. The medical records of all patients were retrospectively reviewed, including patient demographics, cause, location and duration of the colorectal obstruction, clinical efficacy of therapy, occurrence of complications, and mortality. The Institutional Review Board of Severance Hospital approved this study.

4. Statistical analysis

Categorical variables including cause and location of stricture, technical and clinical success, reobstruction, and procedural failure were analyzed using a chi-square or Fisher exact test. Continuous variables, such as age, were analyzed with the Mann-Whitney U test. Variables with p-values of 0.2 or less in the univariate analysis were included in the multivariate logistic regression model. Age and sex were also adjusted for in the logistic regression analysis. For analysis of duration of patency between balloon dilatation and SEMS placement group was compared by using a Kaplan-Meier plot and the log-rank test. p-values of less than 0.05 were considered significant. Statistical analysis was performed using SPSS version 18.0 for Windows (SPSS Inc., Chicago, IL, USA).

RESULTS

1. Patient characteristics

The baseline characteristics of study participants are shown in Table 1. The median age was 58 years (range, 26 to 77 years) in the balloon dilatation group and 62 years (range, 31 to 84 years) in the SEMS group (p=0.626). Men represented 47.2% of the balloon dilatation group and 35.7% of the SEMS group (p=0.462). The patients with the Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 were more common in

Table 1. Baseline Characteristics of Patients and Lesions Treated with Balloon Dilatation or Self-Expandable Metal Stent Placement

Variable	Balloon dilatation (n=36)	SEMS placement (n=14)	p-value
No. of session	65	17	
Age, yr	58 (26–77)	62 (31–84)	0.626
Sex			0.462
Male	17 (47.2)	5 (35.7)	
Female	19 (52.8)	9 (64.3)	
ECOG-PS			0.011
0, 1	30 (83.3)	6 (42.9)	
2, 3, 4	6 (16.7)	8 (57.1)	
Underlying disease			
Hypertension	6 (16.7)	6 (42.9)	0.071
Diabetes	4 (11.1)	2 (14.3)	>0.999
Chronic kidney disease	1 (2.8)	0	NA
Inflammatory disease	4 (11.1)	0	NA
Previous malignancy	31 (86.1)	13 (92.9)	0.663
Cause of colorectal stricture			0.705
Anastomotic stricture	24 (66.7)	10 (71.4)	
Radiation	5 (13.9)	3 (21.4)	
Inflammatory disease*	4 (11.1)	0	
Ischemia	3 (8.3)	1 (7.1)	
Location of stricture			0.875
Rectum	20 (55.6)	8 (57.1)	
Sigmoid colon	10 (27.8)	3 (21.4)	
Descending colon	1 (2.8)	0	
Transverse colon	5 (13.9)	3 (21.4)	
Length of stricture, cm			0.252
<4	30 (83.3)	9 (64.3)	
≥4	6 (16.7)	5 (35.7)	

Data are presented as number (%) or median (range).
SEMS, self-expandable metal stent; ECOG-PS, Eastern Cooperative Oncology Group performance status; NA, not applicable.
*Inflammatory disease includes inflammatory bowel disease, intestinal tuberculosis, and diverticulitis.

Table 2. Short-Term Clinical Efficacy and Complications of Balloon Dilatation and Self-Expandable Metal Stent Placement

Variable	Balloon dilatation	SEMS placement	p-value
Short-term clinical efficacy			
Technical success	64 (98.5)	16 (94.1)	0.374
Clinical success*	57 (89.1)	14 (87.5)	>0.999
Reobstruction[†]	31 (54.4)	8 (57.1)	>0.999
Procedural failure	39 (60.0)	11 (64.7)	0.723
Complication			
Perforation	2 (3.1)	0	NA
Fistula	1 (1.5)	0	NA
Bleeding	0	0	NA
Migration[‡]	NA	5 (31.3)	NA
Total	65	17	

Data are presented as number (%).
SEMS, self-expandable metal stent; NA, not applicable.
*The clinical success rate was calculated as the percentage of the sessions resulting in technical success; [†]The reobstruction rate was calculated as the percentage of sessions resulting in clinical success; [‡]The migration rate was calculated as the percentage of the 16 sessions resulting in technical success.

the balloon dilatation group than in the SEMS group (83.3% vs 42.9%, p=0.011). Anastomotic stricture was the main cause of benign colorectal strictures in both groups (balloon vs SEMS, 66.7% vs 71.4%; p=0.705), followed by radiation, ischemia, and inflammatory disease. Most strictures were located at the rectum in both groups.

2. Short-term clinical efficacies and complications

The overall technical and clinical success rates were similar in both groups (Table 2). In the balloon dilatation group, 98.5% of cases resulted in technical success and in 89.1% of cases clinical success was also achieved. In the SEMS group, 94.1% and

87.5% achieved technical and clinical success, respectively. In the SEMS group, five uncovered stents and 11 covered stents were used. The guidewire could not be inserted in one patient.

Reobstruction occurred in 54.4% of patients in the balloon dilatation group and in 57.1% of the SEMS group (p>0.999). In the balloon dilatation group, perforation and fistula occurred during two (3.1%) and one (1.5%) of the sessions, respectively (Table 2). One perforation occurred during balloon dilatation for postoperative stricture at the transverse colon, and it was treated with surgery. The other perforation developed in a patient with ischemia-induced rectal stricture. The patient's complication was completely resolved by conservative care including fasting, hydration, and antibiotics. In the SEMS group, stent migration occurred in 31.3% of cases (n=5; one uncovered and four covered stents). There were no cases of mortality related to the procedure.

3. Predictive factors for clinical success and risk factors for procedural failure

In the balloon dilatation group, univariate analysis demonstrated that good functional performance (ECOG 0 or 1) was a significant predictive factor for clinical success (p=0.018, data not shown). Age, sex, cause of colorectal stricture, location of stricture, length of stricture, and previous endoscopic treatment were not significantly related to clinical success. In the SEMS group, no significant predictive factors were identified.

In the balloon dilatation group, the univariate analysis showed that having a radiation-related stricture was a sig-

Table 3. Risk Factors for Procedural Failure Following Balloon Dilatation or Self-Expandable Metal Stent Placement*

Variable	Balloon dilatation						SEMS placement		
	No.	Procedural failure	Univariate p-value	Multivariate			No.	Procedural failure	Univariate p-value
				OR	95% CI	p-value			
Age, yr			0.543						>0.999
Young (<65)	32	18 (56.3)		1	-		9	6 (66.7)	
Old (≥65)	33	21 (63.6)		0.560	0.140–2.242	0.413	8	5 (62.5)	
Sex			>0.999						>0.999
Male	35	21 (60.0)		1	-		6	4 (66.7)	
Female	30	18 (60.0)		0.245	0.053–1.135	0.072	11	7 (63.6)	
ECOG-PS			0.158						0.304
0, 1	49	27 (55.1)		1	-		7	6 (85.7)	
2, 3, 4	16	12 (75.0)		2.170	0.446–10.547	0.337	10	5 (50.0)	
Cause of colorectal stricture			0.014						>0.999
Anastomotic stricture	41	23 (56.1)		1	-		11	7 (63.6)	
Radiation	13	12 (92.3)		20.122	1.862–217.469	0.013	4	3 (75.0)	
Inflammatory disease[†]	5	1 (20.0)		0.070	0.004–1.242	0.070	0	0	
Ischemia	6	3 (50.0)		0.428	0.047–3.918	0.453	2	1 (50.0)	
Location of stricture			0.832						0.322
Rectum	37	23 (62.2)					10	8 (80.0)	
Sigmoid colon	18	10 (55.6)					3	1 (33.3)	
Descending colon	4	3 (75.0)					0	0	
Transverse colon	6	3 (50.0)					4	2 (50.0)	
Length of stricture, cm			0.177						0.644
<4	54	30 (55.6)		1	-		10	7 (70.0)	
≥4	11	9 (81.8)		13.581	1.040–177.394	0.047	7	4 (57.1)	
Previous endoscopic treatment			0.310						>0.999
Presence	30	20 (66.7)					9	6 (66.7)	
Absence	35	19 (54.3)					8	5 (62.5)	

Data are presented as number (%).
SEMS, self-expandable metal stent; OR, odds ratio; CI, confidence interval; ECOG-PS, Eastern Cooperative Oncology Group performance status.
*Procedural failure included technical failure, clinical failure, and reobstruction, which required additional endoscopic treatment or surgery; [†]Inflammatory disease includes inflammatory bowel disease, intestinal tuberculosis, and diverticulitis.

nificant risk factor for procedural failure (p=0.014) (Table 3). Multivariate analysis showed that having a radiation-related stricture (odds ratio [OR], 20.122; 95% confidence interval [CI], 1.862 to 217.469) and having a stricture over 4 cm in length (OR, 13.581; 95% CI, 1.040 to 177.394) were independent risk factors for procedural failure, even when controlling for other important factors. Age, sex, ECOG performance status, location of stricture, and previous endoscopic treatment were not significantly related to procedural failure. In the SEMS group, no significant risk factor was identified.
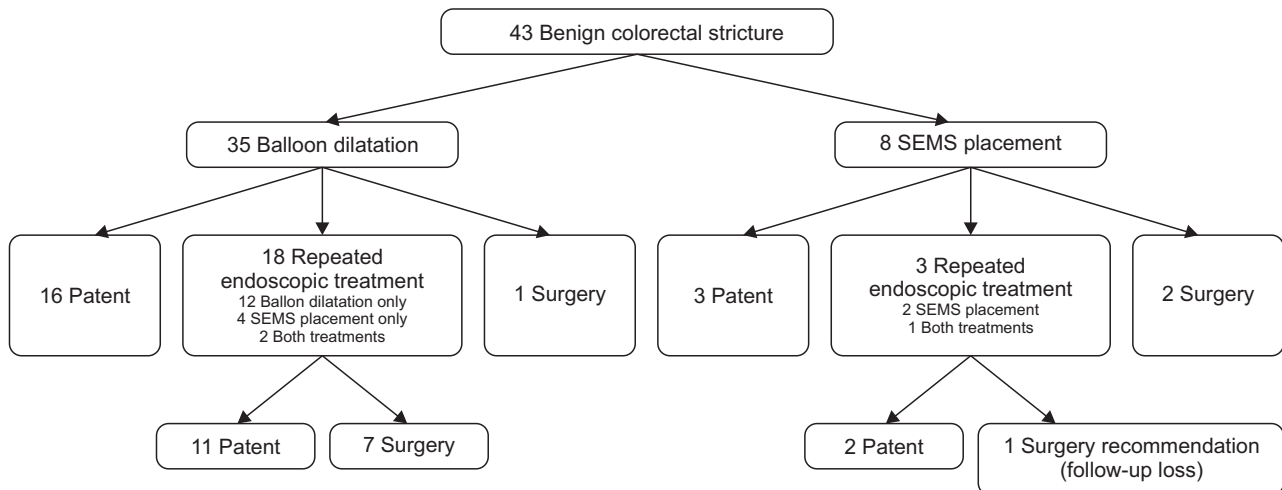
4. Clinical course of patients

Clinical course of patients enrolled in this study was presented in Fig. 1. In 35 patients who had undergone balloon dilatation as an initial treatment, 18 (51.4%) underwent additional endoscopic treatments. In comparison, in eight patients who had received SEMS placement as an initial treatment, three (37.5%) were treated with additional endoscopic treatments. Finally, endoscopic treatment failure was observed in 3 of 29 (10.3%), 2 of 7 (28.6%), and 6 of 7 (85.7%) in the patients underwent balloon dilatation only, SEMS placement only, and both treatments, respectively. Of the total 11 patients with endoscopic treatment failure, seven underwent either ileostomy or colostomy for obstruction following endoscopic treatment failure. Another three patients underwent segmental resection or Hartmann operation. The remaining one patient refused additional treatment and was lost to follow-up.

5. Duration of patency

In order to assess duration of patency according to the en-

Fig. 1. Clinical course of patients enrolled in this study.
SEMS, self-expandable metal stent.
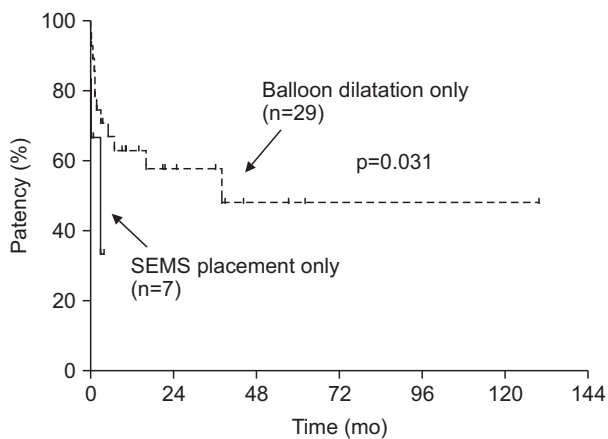
Fig. 2. Kaplan-Meier plots of the patency of initial endoscopic treatments in 29 patients who underwent balloon dilatation only and seven patients who underwent self-expandable metal stent (SEMS) placement only.

doscopic treatment modality, we compared duration of patency between 29 patients who underwent balloon dilatation only and seven patients who underwent SEMS placement only. The median follow-up period was 10.2 months (range, 0 to 130.0 months) in the balloon dilatation group and 0.3 months (range, 0 to 2.9 months) in the SEMS group. Patency was of longer duration in the balloon dilatation group than in the SEMS group (65.5±13.3 months vs 2.0±0.6 months, p=0.031) (Fig. 2).

DISCUSSION

The present study demonstrates that balloon dilatation had favorable clinical outcomes, with an 89.1% rate of initial success and 4.6% rate of procedure-related complications in the setting of benign colorectal strictures.

Benign colorectal strictures occur frequently after colorec-

tal surgery for both benign and malignant disease.[3,8-13] The rectum is the most common site of anastomotic strictures and is treated according to the severity of symptoms.[9,11-13] Before the popularization of endoscopic balloon dilatation, dilatation was performed using rubber bougies, Foley catheter balloons, esophageal dilators, and other metal dilators in patients with severe strictures.[22,23] In contrast with the longitudinal bougienage, only radially directed forces are applied with balloon dilatation. Therefore, the risk of viscus perforation is decreased, and the endoscopic approach with TTS also allows for direct visualization of the stricture and the procedure.[14] Recent studies with endoscopic balloon dilatation have reported that among small samples of patients with anastomotic strictures, there is a 91.7% to 100% initial success rate.[8,9] These studies also demonstrate favorable long-term clinical efficacy, with only 5.9% to 18.2% of patients with successful dilatation experiencing recurrence of symptomatic strictures.[8,9] However, available data suggest that the long-term patency of balloon dilatation is dependent on the cause of the benign stricture. Although endoscopic balloon dilatation showed good immediate efficacy in patients with Crohn's disease, 56% of patients experienced recurrences.[16] The present study revealed that radiation-induced stricture may also be a poor indication for endoscopic treatment, as 92.3% of patients with radiation-induced stricture experienced reobstruction. Another advantage of endoscopic balloon dilatation is that it can be performed repeatedly for patients with recurrence after initial success. In previous studies, all of the recurrences of anastomotic strictures were successfully treated with repeat balloon dilatation.[8,11] Among patients with Crohn's disease, 46% of patients received a new dilatation, and ultimately, 76% of patients were able to avoid surgical treatment.[16] In the present study, an average of 1.8 sessions of balloon dilatation was performed per patient, and ultimately, 75% of patients with various causes of benign colorectal strictures were able to avoid surgical treat-

ment.

Endoscopic balloon dilatation has been shown to be a safe procedure. However, perforation is the most serious complication related to balloon dilatation. One previous study reported an 8.7% rate of all complications requiring hospitalization, including a 4.3% rate of perforation in patients with Crohn's disease.[13] The present study also confirmed the general safety of the balloon dilatation procedure. Even so, perforation occurred at a rate of 3.1% per session and 5.6% per patient, and one patient required emergent surgical treatment. Choice of adequate balloon size according to the diameter of the stricture and a slow increase in balloon pressure, especially after visualization of the balloon in contact with the viscus wall might reduce the risk of perforation. Notably, after successful dilatation, the forceful advancement of the scope across the stricture can cause perforation and should be avoided when possible.

Unfortunately, the present study showed poor efficacy of SEMS in patients with benign colorectal strictures. Considering recent advances and clinical outcomes of SEMS in malignant disease, this is disappointing.[13,24] Although the initial success rate of SEMS was high, the present study showed that patency was significantly shorter than that following balloon dilatation. Another limitation of SEMS for benign stricture is the high complication rate, up to 71.4% of patients in studies reported in the literature.[25] Stent migration is one of the major complications, and 31.3% of patients experienced it in the present study. One recent pilot study of patients with Crohn disease reported a rate of stent migration as high as 60%.[26] Although stent-related perforation did not occur in the present study, it is the most serious complication. Previous studies have reported rates 28.6% for perforation and 4.8% for mortality in patients undergoing this procedure with benign colorectal strictures.[6] Thus, at this point, SEMS is not a reasonable alternative therapy for benign colorectal strictures.

The present study was not without limitations; it suffers from retrospective design and a relatively small sample size. For these reasons, the baseline characteristics of the two study groups were not able to be controlled or randomized. The poor baseline performance status of the patients in the SEMS group might have contributed to the observed poor long-term clinical efficacy. We think that it is difficult to draw a definite conclusion based on this retrospective study. This study, however, has a larger sample size compared to earlier studies.[3-13] Therefore, it might be helpful to select an endoscopic treatment option in patients with benign colorectal strictures. Although the study showed duration of patency was longer in the balloon dilatation group than in the SEMS group, short follow-up duration and relatively high proportion of censored data (62.5%) in the SEMS group were additional limitations. In order to guarantee superiority of balloon dilatation for patency, therefore, long-term follow-up data should be needed. However, we think that balloon dilatation may be acceptable as an initial treatment op-

tion for benign colorectal stricture, because it is easy to undergo additional endoscopic treatment when the balloon dilatation was performed firstly.

In conclusion, endoscopic balloon dilatation is a safe and an effective treatment for benign colorectal strictures. We recommend endoscopic balloon dilatation as an initial therapeutic option for benign colorectal strictures and as an alternative treatment after recurrence. Further study is mandatory to determine whether there is a role for SEMS in patients with benign colorectal strictures.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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