ORIGINAL ARTICLE

INTESTINAL RESEARCH

pISSN 1598-9100 • eISSN 2288-1956
https://doi.org/10.5217/ir.2024.00143
Intest Res 2025;23(3):302-308

Endoscopic radial incision and cutting using balloon-assisted enteroscopy for small intestinal stenosis related to Crohn's disease: a pilot study

Rintaro Moroi[1], Kotaro Nochioka[2], Satoshi Miyata[3], Hideya Iwaki[1], Hirofumi Chiba[4], Hiroshi Nagai[1], Yusuke Shimoyama[1], Takeo Naito[1], Hisashi Shiga[1], Masaki Tosa[5], Yoichi Kakuta[1], Shoichi Kayaba[4], Seiichi Takahashi[5], Yoshitaka Kinouchi[1], Atsushi Masamune[1]

[1]Division of Gastroenterology, Tohoku University Hospital, Sendai, Japan; [2]Clinical Research, Innovation and Education Center, Tohoku University Hospital, Sendai, Japan; [3]Graduate School of Public Health, Teikyo University, Tokyo, Japan; [4]Division of Gastroenterology, Iwate Prefectural Isawa Hospital, Oshu, Japan; [5]Division of Gastroenterology, Iwaki City Medical Center, Iwaki, Japan

Background/Aims: Radial incision and cutting (RIC) is an alternative dilation method for stenosis of the lower gastrointestinal tract. However, its safety and efficacy for the small intestine requiring balloon-assisted enteroscopy (BAE) remain limited. Therefore, this pilot study aimed to evaluate the safety and efficacy of RIC using BAE. **Methods:** We included 10 patients with Crohn's disease and performed 12 sessions of RIC for 10 lesions. The rate of adverse events 1 month after RIC was the primary outcome, whereas short- and long-term prognoses and improvements in subjective symptoms that were evaluated using a visual analog scale were the secondary outcomes. **Results:** The technical success rate for RIC, defined as scope passage immediately following the procedure, was 100% (12/12). The rates of delayed bleeding and perforation were 0% (0/12). One patient developed restenosis because of the worsening of Crohn's disease and underwent surgery 2 months after RIC. The cumulative restenosis-, reintervention-, and surgery-free rates at 1 year after RIC were 67.5%, 78.7%, and 90.0%, respectively. Abdominal pain, abdominal bloating, nausea, and difficulties in defecation significantly improved 4 weeks after RIC. **Conclusions:** RIC for small intestine using BAE has the potential to be safe and effective for relieving symptoms (jRCT identifier jRCTs022200040) **(Intest Res 2025;23:302-308)**.

Key Words: Intestines; Crohn disease; Constriction; Pilot projects; Lower gastrointestinal tract

INTRODUCTION

Benign small bowel stenosis is a common complication in clinical practice that can lead to bowel obstruction, requiring urgent intervention. Furthermore, Crohn's disease (CD)-related mucosal healing and surgical anastomosis can cause stenosis of the small bowel.[1-3] Endoscopic balloon dilation (EBD)[4-6] and surgical intervention, including resection of stenosis[7] or strictureplasty,[8] are the standard therapies for stenosis of the small bowel. However, each therapy has certain limitations, necessitating further endoscopic interventions. A previous study has reported the effectiveness of endoscopic stricturotomy using a needle knife for intestinal strictures associated with inflammatory bowel diseases.[9] In contrast, we have investigated a similar technique, known as radial incision and cutting (RIC), and demonstrated its efficacy and safety for managing lower gastrointestinal strictures.[10-12] The term "RIC" was first introduced in a study that evaluated the use of an electrosurgical knife for endoscopic stricturotomy in esophageal strictures.[13] Although the terms "RIC" and "endoscopic stricturotomy" describe closely related procedures, we adopt the term "RIC" in

Received September 11, 2024. **Revised** October 23, 2024.
Accepted October 24, 2024. **Corrected** February 20, 2026
Correspondence to Rintaro Moroi, Division of Gastroenterology, Tohoku University Hospital, 1-1, Seiryo, Aoba-ku, Sendai 980-8574, Japan. E-mail: rinta@med.tohoku.ac.jp

© 2025 Korean Association for the Study of Intestinal Diseases.
This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (https://creativecommons.org/licenses/by-nc/4.0/) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

https://doi.org/10.5217/ir.2024.00143 • Intest Res 2025;23(3):302-308

accordance with the report of Muto et al.[13] in this study.

RIC has several advantages, including the achievement of a relatively larger dilation compared with that achieved through EBD in some cases and improvement in patients' subjective symptoms.[10-12] However, the main target lesions of RIC are usually limited to colonic stenosis and terminal ileal stenosis, as the working length of an endoscopic electrical knife available in Japan (IT knife nano; Olympus, Tokyo, Japan) is only 1,950 mm, which is not compatible with balloon-assisted enteroscopy (BAE). Although many studies have investigated endoscopic stricturotomy for targeting ileo-colonic anastomosis,[9,14,15] current knowledge regarding RIC for stenosis of the small intestine necessitating BAE remains limited. We hypothesized that performing RIC for small intestinal strictures that cannot be reached by a colonoscope is safe, feasible, and effective in patients with CD, and performing RIC in patients with small intestinal strictures may be highly beneficial.

Therefore, this pilot study aimed to investigate the safety, feasibility, and efficacy of RIC for benign stenosis of the small intestine using BAE and a long electric knife, which is not commercially approved in Japan.

METHODS

1. Study Design and Settings

The study design and settings were the same as reported previously.[16] This physician-initiated, pilot, prospective single-center, and single-arm interventional trial included patients from 3 hospitals (Tohoku University Hospital, Iwaki City Medical Center, and Iwate Prefectural Isawa Hospital).[16] In total, 10 patients with small intestinal strictures were enrolled between October 2021 and February 2024, and RIC was performed in these patients.

The study protocol was approved by the Tohoku Certified Review Board of Tohoku University (Ministry of Health, Labor and Welfare Certified Clinical Research Review Board, Tohoku University) (2021-059). The current protocol is registered in the Japan Registry of Clinical Trials (registration no: jRCTs022200040; URL: https://jrct.niph.go.jp/re/reports/detail/8433). The protocol complied with the Declaration of Helsinki. All patients provided the written informed consent.

2. Participants Eligibility

Cases with the following stricture characteristics were included: (1) strictures through which a balloon-assisted enteroscope could not pass; (2) length of the stricture ≤2 cm (estimated using fluoroscopy); and (3) benign strictures without abscess or fistula. Intestinal strictures were classified into 2 types—primary stricture (disease-related stricture) and secondary stricture (anastomotic stricture after intestinal resection)—based on the cause of formation. Both stricture types were included in this study. The main exclusion criteria were cases with (1) stenosis of >2 cm, (2) abscess or fistula close to stenosis, or (3) malignant stenosis. The presence of ulcers at the site of the stenosis was not defined as an exclusion criterion in the study protocol. Biopsy specimens were obtained to rule out malignant obstruction if necessary.

3. Trial Intervention

The RIC procedure was performed as described previously.[10,11] Fig. 1 presents a representative case of RIC (Supplementary Video 1). We contracted a collaborative research agreement with Fujifilm Corporation and used a long electrosurgical knife (FlushKnife BTS long type; Fujifilm, Tokyo, Japan) with a working length of 2,300 mm and compatibility with BAE. Notably, this long electrosurgical knife is not yet commercially approved in Japan. The settings of the electrosurgical unit (VIO300D; ERBE Electromedicine GmbH, Tübingen, Germany) were the same as those used for endoscopic submucosal dissection of colorectal tumors (ENDO CUT I effect 3, duration 2, cutting duration 2, Swift COAG effect 3, 45 W). Endoscopists who had performed >50 cases of colorectal endoscopic submucosal dissection conducted RICs.

The protocol for this study allows for 3 potential reintervention options (EBD, surgery, or re-RIC) in cases of restenosis. The choice of reintervention is determined in consultation with the participant, taking their preferences into consideration.

4. Outcomes

The primary outcome of this study was the safety of RIC with BAE, involving the frequency of adverse events of special interest (AESI) 1 month after RIC. AESI included complications related to RIC, such as delayed bleeding and perforation, ultimately requiring endoscopic hemostasis or surgery. Technical success rate and procedural time of RIC; improvement of subjective symptoms including abdominal pain, abdominal bloating, nausea, and difficulty in defecation evaluated using the visual analog scale; and long-term prognosis after RIC, including cumulative reintervention (defined as re-RIC, EBD, or surgery after RIC for symptomatic restenosis) and surgery-free rates, were the secondary outcomes.

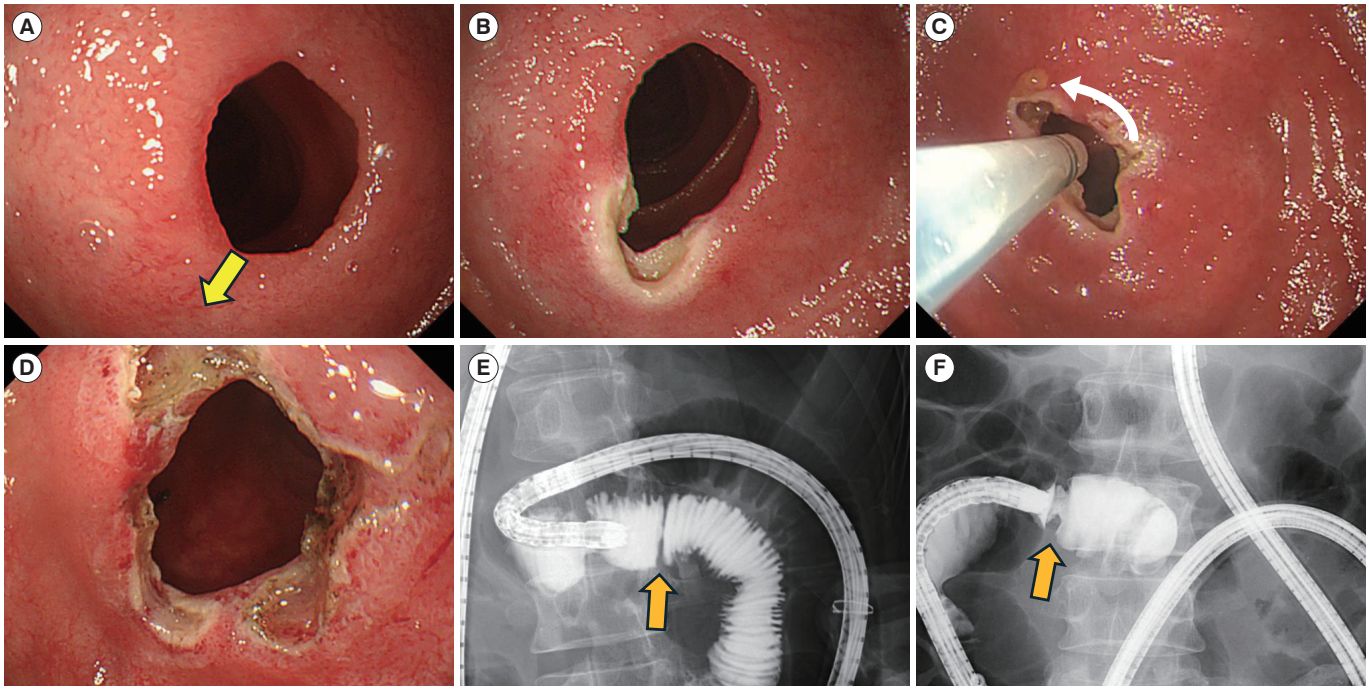

Fig. 1. Procedure of radial incision and cutting (RIC) in a male in his 40s with Crohn's disease having small intestinal stenosis due to mucosal healing of Crohn's disease. (A) Primary stenosis in the small intestine. First radial incision (yellow arrow). (B) Just after first radial incision. (C) Subsequent horizontal cut (white arrow) after radial incision. Regarding the depth of incision, several incisions should be performed with caution not to incise too deep. (D) Completion of RIC. We repeated several radial incisions and horizontal cuttings and completed RIC. An enteroscope could pass through the dilation site. When executing the horizontal cut, slightly angling the scope toward the muscle layer can facilitate smoother manipulation. (E) Fluoroscopy before RIC. Visible stenosis (orange arrow). (F) Fluoroscopy just after the completion of RIC showing adequate dilation and no leakage (orange arrow).

5. Statistical Analysis

Summary statistics were expressed as the mean ± standard deviation (SD), median (interquartile range), or numbers (percentages). Discrete variables were expressed as frequencies. Event rates were estimated using the Kaplan-Meier method. Continuous variables were expressed as the mean ± SD. Improvements in subjective symptoms were evaluated using a paired *t*-test. Statistical significance was defined at a two-sided *P*-value of <0.05. All analyses were performed using R v.4.4.1 (R Foundation, Vienna, Austria).[17]

RESULTS

1. Patient Characteristics

Table 1 presents the baseline characteristics of the study participants. Although patients with other benign diseases were eligible for participation, all study participants had CD. The mean age of the patients was 31.7 years, and they had CD for a mean duration of 13.6 years. Three and 7 patients had primary and secondary stenosis, respectively. Furthermore, 3 patients

Table 1. Baseline Characteristics of Study Population

Characteristic	Value (n = 10)
Male sex	10
Age (yr)	31.7 ± 8.2
Underlying disease, CD	10
Duration of CD (yr)	13.6 ± 11.0
Stenosis site (no. of lesions)	10
Intestinal stricture (primary:secondary)	3:7
Length of the stenosis, ≤ 1 cm	10
Previous history of EBD	3
Ulceration on the stenosis	1
Administration of medication for CD	
Infliximab	4
Azathioprine	3
5-Aminosalicylic acid	2
Central parenteral nutrition	1
Duration of follow-up after RIC (day)	373 (318.5–595.3)

Values are presented as mean ± SD or median (IQR).
CD, Crohn's disease; EBD, endoscopic balloon dilation; RIC, radial incision and cutting; SD, standard deviation; IQR, interquartile range.

https://doi.org/10.5217/ir.2024.00143 • Intest Res 2025;23(3):302-308

Table 2. Adverse Events within the 1 Month after RIC (n = 12)

Adverse event	No. (%)
Delayed bleeding	0
Perforation	0
Worsening of CD	1 (8.3)

RIC, radial incision and cutting; CD, Crohn's disease.

Table 3. Short-term Results of RIC

Variable	Result[a]
Technical success rate of RIC (%)	100
Procedure time of RIC (min), mean ± SD	9.6 ± 6.4
Hospital stay after RIC (day), mean ± SD	14.4 ± 7.5

[a]Results from 10 participants, 10 lesions, and 12 sessions of RIC.
RIC, radial incision and cutting; SD, standard deviation.

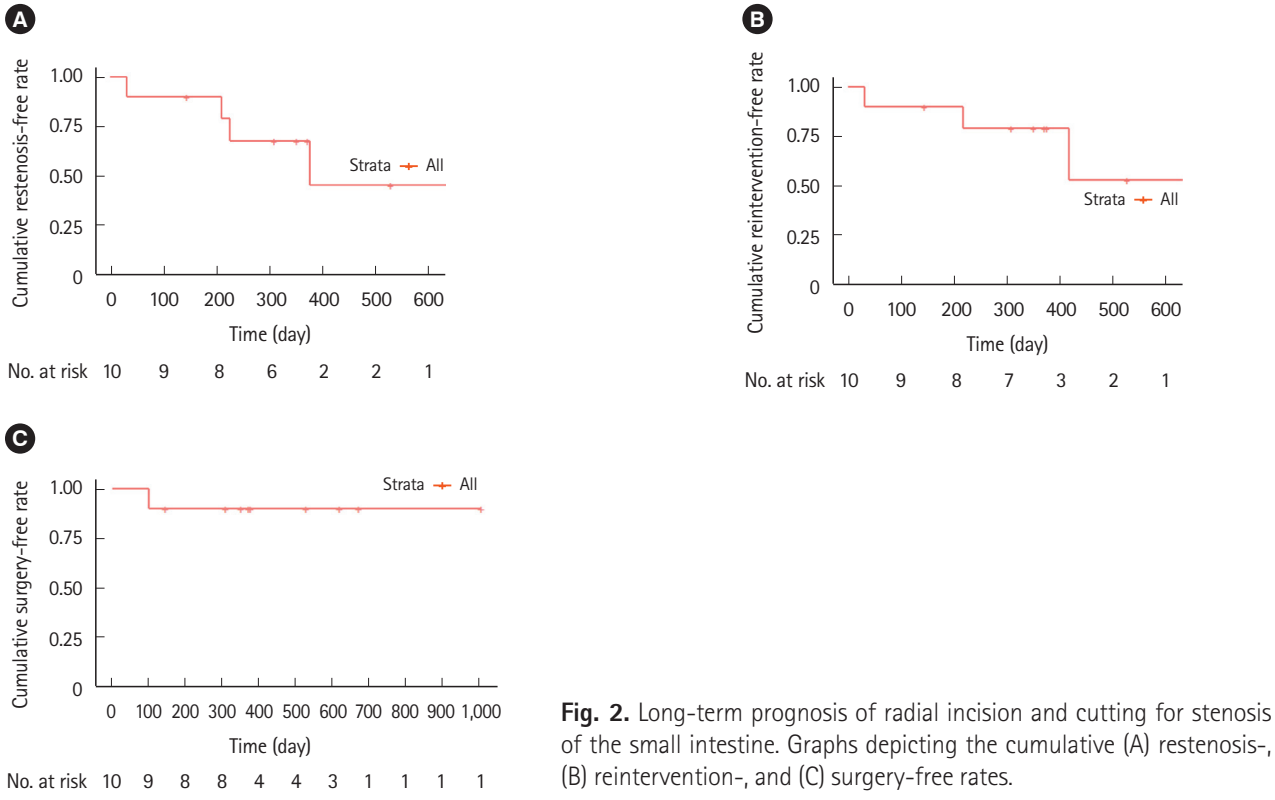

Fig. 2. Long-term prognosis of radial incision and cutting for stenosis of the small intestine. Graphs depicting the cumulative (A) restenosis-, (B) reintervention-, and (C) surgery-free rates.

had a history of EBD, and 1 had stricture ulceration. The length of stenosis in all participants measured 1 cm or less. The treatment for CD comprised infliximab, azathioprine, 5-aminosalicylic acid, and central parenteral nutrition for 4, 3, 2, and 1 patients, respectively. Notably, 2 patients did not receive any treatment.

2. Primary Endpoint

We conducted 12 sessions of RIC for 10 lesions. Table 2 shows the safety profile for 1 month after RIC for small bowel strictures. No patients experienced delayed bleeding and perforation. Thirty-four days after RIC, CD worsened in 1 patient and caused restenosis, which led to bowel obstruction; the patient underwent surgical bowel resection.

3. Short-term Outcomes of RIC of the Small Intestine Using BAE

Table 3 presents the short-term outcomes following RIC of the small intestine. The technical success rate for RIC was 100% (12/12). The mean procedural time for RIC was 9.6 minutes, and the mean duration of hospitalization after RIC was 14.4 days.

4. Long-term Outcomes of RIC of the Small Intestine Using BAE

Fig. 2 shows the long-term outcomes following RIC of the small intestine. The cumulative restenosis-, reintervention-, and surgery-free rates 1 year after RIC were 67.5%, 78.7%, and 90.0%, respectively. Three patients underwent reintervention, including EBD (1 patient) and re-RIC (2 patients), because of reste-

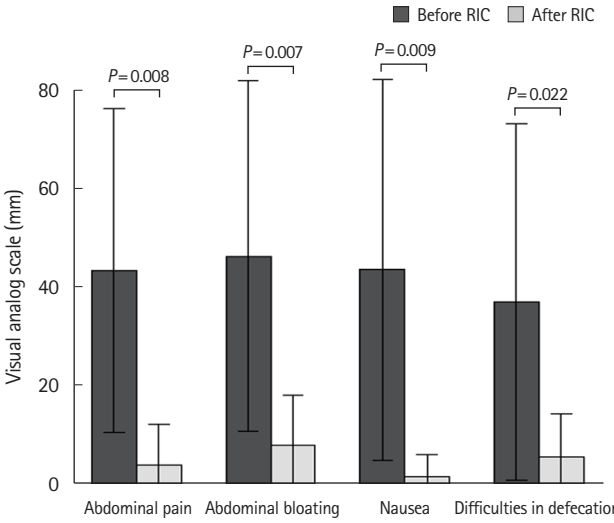

Fig. 3. Subjective symptoms before and 4 weeks after radial incision and cutting (RIC).

nosis. Two months after RIC, 1 patient underwent intestinal resection because of refractory restenosis that was resistant to semi-urgent EBD (the participant hoped for surgery instead of performing re-RIC).

5. Improvement in Subjective Symptoms Following RIC

Improvements in subjective symptoms are summarized in Fig. 3. The symptoms, including abdominal pain (43.6 mm vs. 3.8 mm, $P=0.008$), abdominal bloating (46.5 mm vs. 7.9 mm, $P=0.007$), nausea (43.8 mm vs. 1.6 mm, $P=0.009$), and difficulties in defecation (37.1 mm vs. 5.4 mm, $P=0.022$), significantly improved after RIC.

DISCUSSION

In this pilot study, we investigated the safety and efficacy of RIC for small intestine stenosis using a long electrosurgical knife and BAE. RIC for stenosis of the small intestine demonstrated a low complication rate and high technical success rate and was associated with improved subjective symptoms.

Our results indicated the safety of RIC for the small intestine. Our previous studies have reported a relatively high delayed bleeding rate of approximately 20%.[10-12] Although our previous studies have also shown a relatively high delayed bleeding rate, endoscopic hemostasis was achieved in all cases. However, none of the patients in the present study experienced delayed bleeding after RIC. Furthermore, some previous studies have reported ileocolonic anastomotic strictures due to CD in all patients with delayed bleeding after RIC.[10-12] Conversely, the cases with secondary strictures in this study were all ileal-to-ileal anastomoses; this may be the reason for nonoccurrence of delayed bleeding in this study. Furthermore, no patients experienced perforation in this study. Additionally, a high technical success rate (approximately 100%) and low perforation rate (0%–3.7%) have been reported previously.[10-12] A retrospective study investigating endoscopic stricturotomy for small bowel stenosis using BAE exhibited similar results of high technical success and low adverse event rates.[18] Nevertheless, further investigations with larger sample sizes are necessary to precisely evaluate the safety of RIC.

The short-term outcomes of RIC using BAE were beneficial, with a technical success rate of 100% and a relatively short procedural time. Notably, RIC using BAE may be more difficult to perform than EBD, and the technical success rate may depend on the operator's expertise. Furthermore, significant improvement in subjective symptoms, as observed in this study, is another advantage of RIC. However, this is a pilot study with a single-arm design. Further investigations are required to elucidate the clinical advantages of RIC in comparison with other interventions.

Considering RIC for stenosis of the small intestine is controversial, and in the context of the underlying etiology of stricture formation, only patients with CD were included in this study. RIC has been previously performed for various etiologies, including anastomotic stricture due to colorectal cancer and mucosal healing of ischemic and ulcerative colitis.[11,12] RIC for stenosis in the small intestine may be adapted for various etiologies, including CD. Regarding stricture length, we included patients with stricture length of ≤1 cm. A relatively short stricture length is desirable for RIC, as an incisional procedure cannot be performed for a longer stricture. Notably, RIC is not expected to dilate strictures of >2 cm in length, and EBD may be suitable for such long strictures. However, RIC has the potential to dilate EBD-resistant stenosis by incising severe fibrosis using an electrosurgical knife.

The long-term outcomes of RIC for stenosis in the small intestine were favorable, with the cumulative reintervention- and surgery-free rates at 1 year after RIC of 78.7% and 90.0%, respectively. The reintervention-free rate in this study was higher than those of our previous studies (55.8%–63.7%)[11,12] which included colonic and terminal ileal strictures. Furthermore, the surgery-free rate at 1 year after RIC was comparable to or slightly higher than those reported for EBD for small intestine using BAE (63.1%–87.3%).[19,20] However, the etiologies of stricture formation differed between the present and previ-

https://doi.org/10.5217/ir.2024.00143 • Intest Res 2025;23(3):302-308

ous studies. Therefore, studies including relatively larger cohorts are required to determine the etiologies for which RIC can be performed.

The main aim of endoscopic dilation for the small intestine is to avoid surgery to the extent possible. Considering the low complication and high technical success rate observed in this study, RIC using a long knife and BAE could be an alternative surgical intervention for small intestinal stenosis. However, we did not directly compare the effectiveness of RIC with EBD in symptom relief. Further research, including comparative studies between RIC and EBD, is needed to more accurately assess the feasibility and effectiveness of RIC.

This study has some limitations. First, this prospective study was a single-center pilot study with a small number of participants. Notably, the sample size in this study was too small to determine the safety and efficacy of RIC for stenosis of the small intestine. Second, as RIC is a novel dilation method, the acquisition of technical skills for RIC is necessary, necessitating further investigations with large cohorts to validate the safety, efficacy, and feasibility of RIC for stenosis of the small intestine. Third, the absence of a sham procedure group introduces the potential for bias. Without a sham intervention, a placebo effect may have occurred, whereby participants could have experienced symptom relief due to psychological factors rather than the actual effects of the intervention.

In conclusion, RIC for stenosis of the small intestine using a long electrosurgical knife and BAE has the potential to be safe, effective, and feasible modality for relieving symptoms. Further investigations are warranted.

ADDITIONAL INFORMATION

Correction

This article was corrected on February 20, 2026, to correct a spelling error in Fig. 1.

Funding Source

The authors received no financial support for the research, authorship, and/or publication of this article.

Conflict of Interest

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

Data Availability Statement

Data are available upon reasonable request.

Author Contributions

Conceptualization: Moroi R, Nochioka K. Data curation: Moroi R. Formal analysis: Miyata S. Investigation: Moroi R, Iwaki H, Chiba H, Nagai H, Shimoyama Y, Naito T, Shiga H, Tosa M, Kakuta Y, Kayaba S, Takahashi S. Methodology: Moroi R, Nochioka K. Writing – original draft: Moroi R. Writing – review & editing: Kinouchi Y, Masamune A. Approval of final manuscript: all authors.

Additional Contributions

This study was supported by the Specified Clinical Trials Promotion Program of the Tohoku University Hospital. We thank Ms. Mizue Kusaba (Clinical Research, Innovation and Education Center, Tohoku University Hospital, Sendai, Japan) for her support in this study.

ORCID

Moroi R	https://orcid.org/0000-0002-6759-0135
Nochioka K	https://orcid.org/0000-0001-8297-8624
Miyata S	https://orcid.org/0000-0003-2400-7525
Iwaki H	https://orcid.org/0009-0007-5498-9714
Chiba H	https://orcid.org/0000-0002-7033-3084
Nagai H	https://orcid.org/0009-0000-8782-1909
Shimoyama Y	https://orcid.org/0009-0005-1133-7754
Naito T	https://orcid.org/0000-0002-9744-7946
Shiga H	https://orcid.org/0000-0001-6623-2603
Kakuta Y	https://orcid.org/0000-0002-7042-009X
Takahashi S	https://orcid.org/0009-0003-5137-0781
Kinouchi Y	https://orcid.org/0000-0002-3368-8855
Masamune A	https://orcid.org/0000-0001-7184-7282

Supplementary Material

Supplementary materials are available at the Intestinal Research website (https://www.irjournal.org).

REFERENCES

1. Gordon IO, Bettenworth D, Bokemeyer A, et al. Histopathology scoring systems of stenosis associated with small bowel Crohn's disease: a systematic review. Gastroenterology 2020;158:137-150.e1.
2. Bettenworth D, Bokemeyer A, Baker M, et al. Assessment of Crohn's disease-associated small bowel strictures and fibrosis on cross-sectional imaging: a systematic review. Gut 2019;68:1115-1126.
3. Mak JW, Ng SC. Epidemiology of fibrostenosing inflammato-

ry bowel disease. J Dig Dis 2020;21:332-335.
4. Hirai F. Current status of endoscopic balloon dilation for Crohn's disease. Intest Res 2017;15:166-173.
5. Endo K, Takahashi S, Shiga H, Kakuta Y, Kinouchi Y, Shimosegawa T. Short and long-term outcomes of endoscopic balloon dilatation for Crohn's disease strictures. World J Gastroenterol 2013;19:86-91.
6. 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;12:394-401.
7. Bemelman WA, Allez M. The surgical intervention: earlier or never? Best Pract Res Clin Gastroenterol 2014;28:497-503.
8. Ambe R, Campbell L, Cagir B. A comprehensive review of strictureplasty techniques in Crohn's disease: types, indications, comparisons, and safety. J Gastrointest Surg 2012;16:209-217.
9. Lan N, Shen B. Endoscopic stricturotomy with needle knife in the treatment of strictures from inflammatory bowel disease. Inflamm Bowel Dis 2017;23:502-513.
10. Moroi R, Shiga H, Kuroha M, et al. Endoscopic radial incision and cutting for Crohn's disease-associated intestinal stricture: a pilot study. Endosc Int Open 2020;8:E81-E86.
11. Moroi R, Shiga H, Nochioka K, et al. Endoscopic radial incision and cutting for benign stenosis of the lower gastrointestinal tract: an investigation of novel endoscopic treatment in multicenter trial. J Gastroenterol Hepatol 2022;37:1554-1560.
12. Moroi R, Nochioka K, Miyata S, et al. Safety and effectiveness of additional triamcinolone acetonide with endoscopic radial incision and cutting for benign stenosis of the lower gastrointestinal tract: a pilot study. DEN Open 2024;5:e70002.
13. Muto M, Ezoe Y, Yano T, et al. Usefulness of endoscopic radial incision and cutting method for refractory esophagogastric anastomotic stricture (with video). Gastrointest Endosc 2012;75:965-972.
14. Lan N, Shen B. Endoscopic stricturotomy versus balloon dilation in the treatment of anastomotic strictures in Crohn's disease. Inflamm Bowel Dis 2018;24:897-907.
15. Lan N, Hull TL, Shen B. Endoscopic stricturotomy and ileocolonic resection in patients with primary Crohn's disease-related distal ileum strictures. Gastroenterol Rep (Oxf) 2020;8:312-318.
16. Moroi R, Shiga H, Nochioka K, et al. A pilot study investigating the safety and feasibility of endoscopic dilation using a radial incision and cutting technique for benign strictures of the small intestine: a study protocol. Pilot Feasibility Stud 2022;8:85.
17. R Core Team. A language and environment for statistical computing [Internet]. c2022 [cited 2024 Oct 20]. https://www.r-project.org
18. Ning SB, Yang H, Li B, et al. Balloon-assisted enteroscopy-based endoscopic stricturotomy for deep small bowel strictures from Crohn's disease: first cohort study of a novel approach. Dig Liver Dis 2023;55:1397-1402.
19. Sunada K, Shinozaki S, Nagayama M, et al. Long-term outcomes in patients with small intestinal strictures secondary to Crohn's disease after double-balloon endoscopy-assisted balloon dilation. Inflamm Bowel Dis 2016;22:380-386.
20. Nishida Y, Hosomi S, Yamagami H, et al. Analysis of the risk factors of surgery after endoscopic balloon dilation for small intestinal strictures in Crohn's disease using double-balloon endoscopy. Intern Med 2017;56:2245-2252.