

Efficacy and safety of radial incision and cutting for nonsurgical refractory benign esophageal stricture



Authors

Yosuke Mitani¹, Kenshiro Hirohashi¹, Masashi Tamaoki¹, Akira Yokoyama¹, Chikatoshi Katada¹, Aya Ueda¹, Natsuko Yamahigashi², Hirokazu Higuchi², Manabu Muto¹

Institutions

- 1 Therapeutic Oncology, Kyoto University Graduate School of Medicine Faculty of Medicine, Kyoto, Japan
- 2 Medical Supply, Kyoto University Hospital, Kyoto, Japan

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Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Corresponding author

Manabu Muto, Kyoto University Graduate School of Medicine
Faculty of Medicine, Therapeutic Oncology, Kyoto, Japan
mmuto@kuhp.kyoto-u.ac.jp

ABSTRACT

Background and study aims Radial incision and cutting (RIC) was established to improve refractory esophageal anastomotic strictures but its efficacy and safety for non-surgical refractory strictures remain unclear. To evaluate the usefulness of RIC in nonsurgical refractory strictures, we retrospectively compared outcomes between nonsurgical and surgical strictures.

Patients and methods We retrospectively studied 54 consecutive patients who were initially treated with RIC for refractory benign esophageal stricture. The study variables included dysphasia score improvement rate, frequency of repeated RIC, cumulative patency rate, cumulative stricture improved rate, and adverse events(AEs), which were compared between nonsurgical (n=21) and surgical (n=33) stricture groups.

Results Immediately after RIC, 90.5% of patients in the nonsurgical group and 84.8% of patients in the surgical group had improvement in dysphagia ($P=0.69$). The frequency of intervening repeated RIC was 42.9% in the nonsurgical group and 42.4% in the surgical group ($P=0.98$). During median follow-up of 22.3 months (range, 1.0–175.0), the cumulative patency rate ($P=0.23$) and cumulative stricture improvement rate ($P=0.14$) but there was not statistical difference between the two groups. Despite a low cumulative stricture improvement rate (9.5%) at 6 months after the first RIC in the nonsurgical group, 57.7% of patients no longer required endoscopic balloon dilatation at 2 years. The cumulative stricture improvement rate was significantly lower in patients with a history of radiation therapy. No severe AEs were observed in the nonsurgical group.

Conclusions RIC for nonsurgical refractory benign esophageal stricture is an effective and safe treatment option.

Introduction

Esophageal stricture causes dysphagia, significantly worsening nutritional status and quality of life. Dysphagia occurs especially after surgery, chemoradiotherapy, and widespread endoscopic resection for esophageal cancer [1, 2, 3]. Endoscopic bal-

loon dilatation (EBD) is the standard treatment for benign esophageal stricture, and many patients achieve symptomatic improvement after EBD [1, 4, 5]. However, some patients develop refractory benign esophageal stricture that does not improve with repeated EBD [1, 6, 7].

We previously demonstrated the efficacy and safety of radial incision and cutting (RIC) as a stricture improvement procedure for surgical refractory benign esophageal stricture that does not improve after repeated EBD [8]. After the RIC procedure, 81.3% of patients were able to take solid foods and 93.8% of patients had improvement in dysphagia. In addition, 63% and 62% of the patients were able to take solid foods at 6 months and 12 months, respectively. Based on these results, a Phase 2/3 multicenter randomized controlled trial (JCOG1207, jRCTs031180177) was conducted to compare the efficacy of RIC with local steroid injection compared with EBD with local steroid injection in surgical refractory benign esophageal stricture. In the latest report of this study, RIC with steroid injection was performed safely but did not show superiority to EBD with steroid injection, and thus, the standard treatment is EBD and RIC is positioned as a treatment option for surgical refractory esophageal stricture [9].

On the other hand, a nonsurgical refractory benign esophageal stricture can be caused by radiotherapy, widespread endoscopic resection, photodynamic therapy, reflux esophagitis, and corrosive esophagitis [10, 11, 12]. A case series of RIC for nonsurgical refractory benign esophageal stricture showed dramatic short-term symptomatic improvement and no major complications. However, the long-term patency rate was unfavorable at 37.5% [13]. Therefore, the efficacy and safety of RIC for nonsurgical refractory benign esophageal stricture, especially regarding long-term prognosis, remain unclear.

To evaluate the efficacy and safety of RIC for nonsurgical refractory benign esophageal stricture, we retrospectively compared the clinical outcomes between a nonsurgical stricture group and a surgical stricture group of patients who underwent RIC in our hospital.

Patients and Methods

Participants

Data from patients who were initially treated with RIC for refractory benign esophageal stricture from November 2007 through March 2022 were retrospectively collected in our hospital. Refractory benign esophageal stricture was defined as a benign stricture for which symptoms of dysphagia are not relieved even after three or more repeated EBDs. Based on previous studies [8, 9], when there is no improvement in stricture after three or more EBD procedures, we considered refractory benign esophageal stricture and considered RIC procedures. We defined strictures resulting from treatment of malignant disease as benign if there were no residual tumors. Written informed consent was obtained from all patients for the procedures of RIC and EBD. This study was approved by the institutional review board in our hospital. Informed consent for this study was obtained using an opt-out method.

Study variables

To examine the efficacy and safety of RIC in the nonsurgical stricture group, patients were divided into two groups according to the cause of stricture. Patients whose stricture was caused by surgery were defined as the surgical stricture group,

and those whose stricture was caused by other causes were defined as the nonsurgical stricture group. In patients with multiple causes of stricture, the treatment modality associated with esophageal stricture development was identified by clinical course. The following study variables were compared between the nonsurgical stricture group and surgical stricture group: (1) dysphagia score (DS) improvement rate, (2) frequency of re-RIC and duration between first RIC and re-RIC, (3) cumulative patency rate, (4) cumulative stricture improved rate, and (5) adverse events (AEs).

Evaluation of dysphagia before and after RIC and DS improvement rate

The following DS was used to evaluate the grade of swallowing ability before and after RIC: 0, able to eat a normal diet; 1, unable to swallow certain solids; 2, able to swallow semisolid foods; 3, able to swallow liquids only; and 4, unable to swallow liquid [14]. The DS was collected during an outpatient or in-treatment interview. DS improvement rates were defined as changes in DS over time after the first RIC.

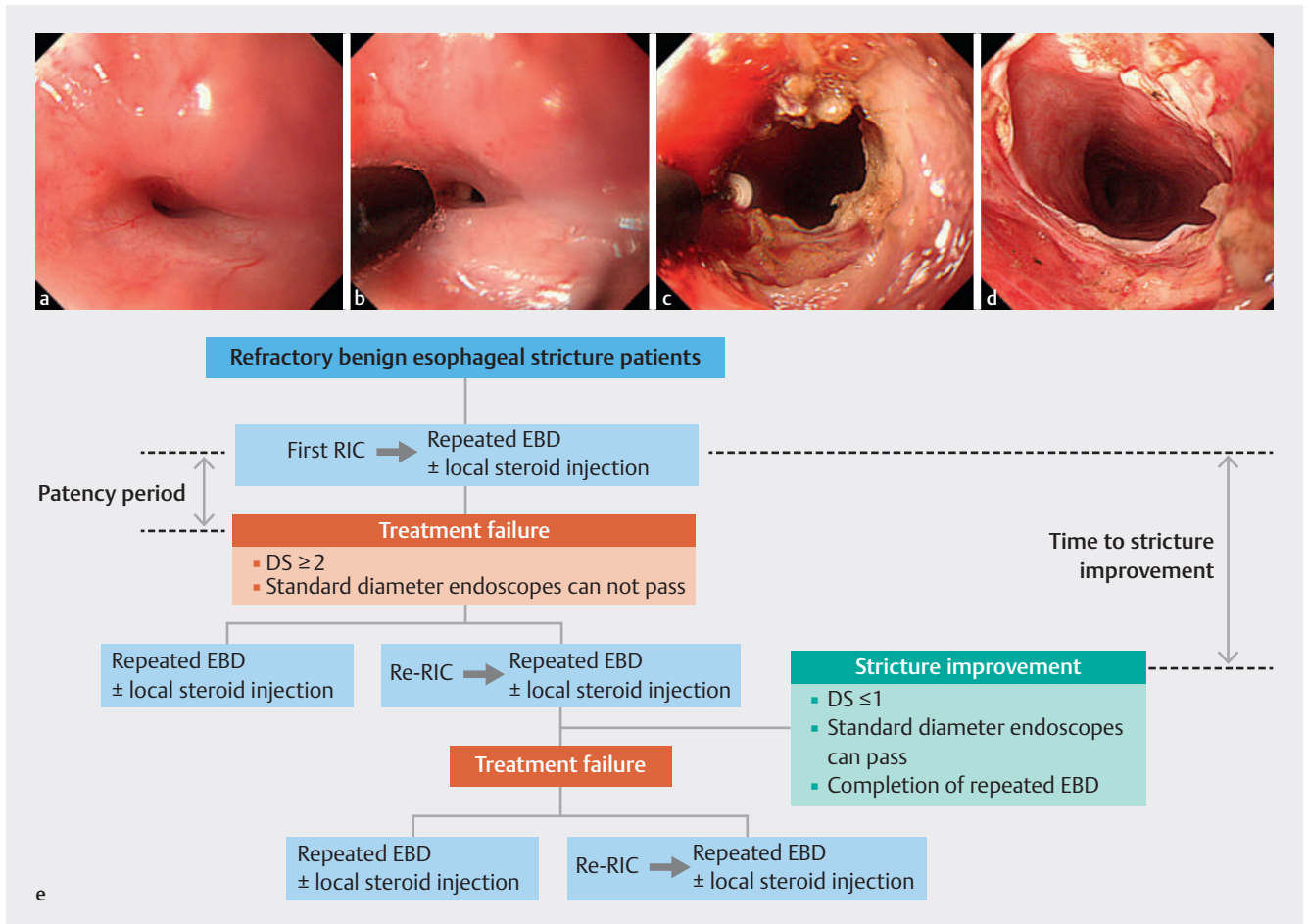
RIC procedure and treatment strategy

RIC was carried out under deep sedation with a combination of midazolam, propofol, and pethidine hydrochloride. The stricture area was incised radially using an IT knife (Olympus, Tokyo, Japan) endoscopically, and the tissue between the incisions was dissected around the stricture [8]. The procedure was performed with the goal of passing a standard endoscope intraoperatively whenever possible. Endoscopic images before and after RIC are shown in ► Fig. 1a, ► Fig. 1b, ► Fig. 1c, and ► Fig. 1d. After RIC, prophylactic EBD was repeated at 1- to 2-week intervals to maintain patency until scar formation. Prophylactic EBD was gently performed during the artificial ulcer phase after RIC. Triamcinolone acetonide, one of the steroids, was injected into an ulceration after RIC and a laceration immediately after EBD.

The treatment strategy for refractory benign esophageal stricture patients is shown in ► Fig. 1e. Repeated EBD was considered to be terminated with DS of ≤ 1 , and a standard diameter scope passing, which was regarded as “stricture improvement”. If the DS was > 2 and the standard diameter scope could not be passed, then the procedure was considered a “treatment failure”, and the attending physician considered re-RIC in light of the patient’s general condition and wishes. We considered the time to treatment failure and the time to stricture improvement to be important RIC endpoints, which we defined and evaluated as described below.

Definition of treatment failure and cumulative patency rate

Treatment failure of the RIC procedure was defined as inability to pass a standard endoscope with a diameter of 8.9 mm or larger (Q240, 1T240, H260, H260Z, H290, and H290Z; Olympus Medical Systems, Tokyo, Japan) through the stricture site after RIC and as the presence of dysphagia with a score of ≥ 2 . The patency period, used in the analysis of cumulative patency rates,



► **Fig. 1** Treatment strategy for refractory benign esophageal stricture patients. **a, b, c, d** A case of refractory esophageal stricture after chemoradiotherapy for esophageal cancer. **a** Severe stricture before the treatment. **b** Several incisions using the IT knife. **c** Dissection of the entire circumference of the stricture. **d** Removal of hard necrotic tissue from the structure. **e** Schema of treatment strategy. Patency period: The period from the date of first RIC to the date of earliest treatment failure. Time to stricture improvement: The period from the date of the first RIC to the date of the last EBD. RIC, radial incision and cutting; EBD, endoscopic balloon dilatation; DS, dysphasia score; re-RIC, repeated RIC.

was defined as the period from the date of first RIC to the date of earliest treatment failure (► **Fig. 1e**).

Definition of stricture improvement and cumulative stricture improved rate

Because repeated EBD over time affects patient quality of life, achieving stricture improvement to the point where periodic EBD is no longer necessary is an important treatment endpoint. We defined achievement of stricture improvement as DS1 or less for at least 6 months, passable by standard endoscopy, and no need for repeated EBD. Time to stricture improvement, used in the analysis of cumulative stricture improvement rates, was defined as the period from the date of the first RIC to the date of the last EBD. The day that resulted in stricture improvement was used in the analysis of cumulative stricture improved rates (► **Fig. 1e**).

Evaluation of the diameter and length of the stricture

The diameter of strictures was categorized as follows: (1) an endoscope with a 10-mm size could pass through the stricture, (2) from 2 mm to < 10 mm, and (3) < 2 mm. Stricture size was measured based on contrast to the tip (2.2 mm) of the IT knife. The length of stricture before RIC was categorized as follows: (1) < 5 mm and (2) > 5 mm. Stricture length was calculated from the width of the notch shown fluoroscopically on the balloon at the time of the EBD.

Evaluation of RIC safety

Safety of RIC was evaluated in terms of procedure time, hospitalization period, and AEs. AEs were evaluated by the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0, and Grade 2 or higher was treated as a serious AE.

Table 1 Characteristics of patients with esophageal stricture undergoing radial incision and cutting.

| | All | Nonsurgical stricture | | Surgical stricture | | P value |
|---|------------------------|------------------------|----|-----------------------|----|----------|
| | n = 54 | n = 21 | | n = 33 | | |
| Age, median (range) | 68 (33–86) | 71 (47–86) | | 67 (33–83) | | 0.37 |
| Gender (M/F) | 42/12 | 16/5 | | 26/7 | | 0.82 |
| EBD period before RIC median (range) | 6.6 months (1.2–102.4) | 6.7 months (1.8–202.4) | | 6.6 months (1.2–61.7) | | 0.74 |
| EBD count before RIC, median (range) | 9 (3–41) | 10 (3–41) | | 8 (3–20) | | 0.14 |
| EBD ≥ 6 before RIC | 39 (72.2%) | 18 (85.7%) | | 21 (63.6%) | | 0.12 |
| Estimated diameter of stricture | | | | | | 0.89 |
| 2 to ≤ 10 | 40 | 16 | | 24 | | |
| < 2 | 14 (25.9%) | 5 (23.8%) | | 9 (27.2%) | | |
| Stricture length > 5 mm | 12 (22.2%) | 6 (28.6%) | | 6 (18.2%) | | 0.32 |
| History of radiation therapy to esophagus | 16 (29.6%) | 15 (71.4%) | | 1 (3.0%) | | < 0.0001 |
| Cause of stricture | | Chemoradiotherapy | 10 | Esophagectomy | 30 | |
| | | Endoscopic resection | 4 | Proximal gastrectomy | 2 | |
| | | Photodynamic therapy | 4 | Total gastrectomy | 1 | |
| | | Reflux esophagitis | 1 | | | |
| | | Corrosive esophagitis | 2 | | | |

EBD, endoscopic balloon dilatation; RIC, radial incision and cutting.

Statistical analysis

Patient clinical characteristics, DS, timing, and frequency of re-RIC and safety items were evaluated for differences between the two groups using Fisher's exact test or Wilcoxon test. The cumulative patency rates and the cumulative stricture improvement rates were estimated using the Kaplan–Meier method and comparisons were made with Log-rank test. Follow-up was terminated upon death or cancer recurrence, and in the case of missed visits, follow-up was concluded on the date of the last outpatient visit. Multivariate analysis of subgroups in the nonsurgical group was estimated using Cox regression analysis to compare hazard ratios. All *P* values were 2-sided, and *P* < 0.05 was considered significant. All data were analyzed using GraphPad Prism10 (GraphPad Software, Boston, Massachusetts, United States).

Results

Participants

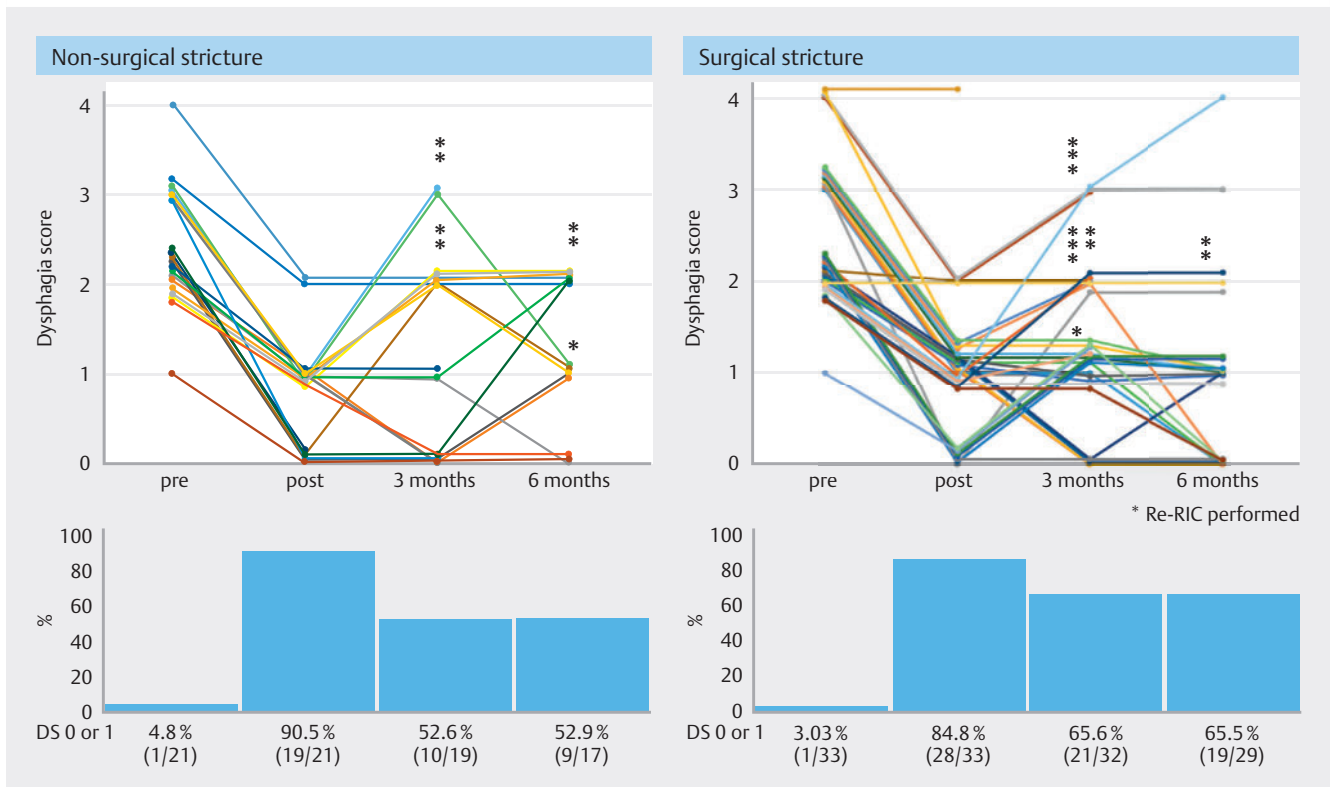
A total of 54 patients with refractory benign esophageal stricture underwent RIC in our hospital. The demographic characteristics of the 54 patients and the characteristics of their strictures according to the cause of stricture are presented in ► **Table 1**. In the surgical stricture group (*n* = 33), the cause of the stricture was esophagectomy in 30 patients, proximal gastrectomy in two patients, and total gastrectomy in one patient. In the nonsurgical stricture group (*n* = 21), the causes of stricture

were chemoradiation in 10 patients, endoscopic submucosal dissection or endoscopic mucosal resection in four patients, photodynamic therapy in four patients, and esophagitis in three patients. In the nonsurgical stricture group, 15 patients (71.4%) had a history of radiation therapy to the esophagus, compared with only one patient (3.0%) in the surgical stricture group (*P* < 0.0001).

DS improvement over time and re-RIC intervention

Immediately after RIC, there was one case in the surgical stenosis group and one case in the nonsurgical stenosis group in which the scope failed to pass; however, 90.5% of patients in the nonsurgical stricture group and 84.8% of patients in the surgical stricture group showed improvement in dysphagia (*P* = 0.69). Six months after RIC, 52.9% of patients in the nonsurgical stricture group and 65.5% of patients in the surgical stricture group were able to maintain solid food intake without re-RIC (► **Fig. 2**).

In the nonsurgical stricture group and surgical stricture group, the frequency of intervening re-RIC was 42.9% and 42.4%, respectively (*P* = 0.98). Median duration between first RIC and re-RIC was 7.9 months (range, 0.5–14.9 months) and 2.8 months (range, 0.9–9.6 months), respectively (*P* = 0.53). The frequency of three or more RIC was 14.3% and 24.2%, respectively (*P* = 0.60) (► **Table 2**).



► **Fig. 2** Changes over time in dysphagia score in the short term after the first radial incision and cutting. re-RIC are indicated by red stars, and the number of red stars indicates the number of re-RIC within 3 and 6 months, respectively. DS, dysphasia score; re-RIC, repeated RIC.

► **Table 2** Treatment profiles for radial incision and cutting.

| | All n = 54 | Nonsurgical stricture n = 21 | Surgical stricture n = 33 | P value |
|-----------------------------------|--------------------------|---------------------------------|------------------------------|---------|
| Frequency of re-RIC | 42.6% (23/54) | 42.9% (9/21) | 42.4% (14/33) | 0.98 |
| Median duration to re-RIC (range) | 4.0 months (0.5–14.9) | 7.9 months (0.5–14.9) | 2.8 months (0.9–9.6) | 0.53 |
| Number of RIC (median, range) | 1 | 1 (1–8) | 1 (1–7) | 0.6 |
| 1 | 31 | 12 | 19 | |
| 2 | 12 | 6 | 6 | |
| 3 | 0 | 0 | 4 | |
| > 3 | 7 | 3 | 4 | |

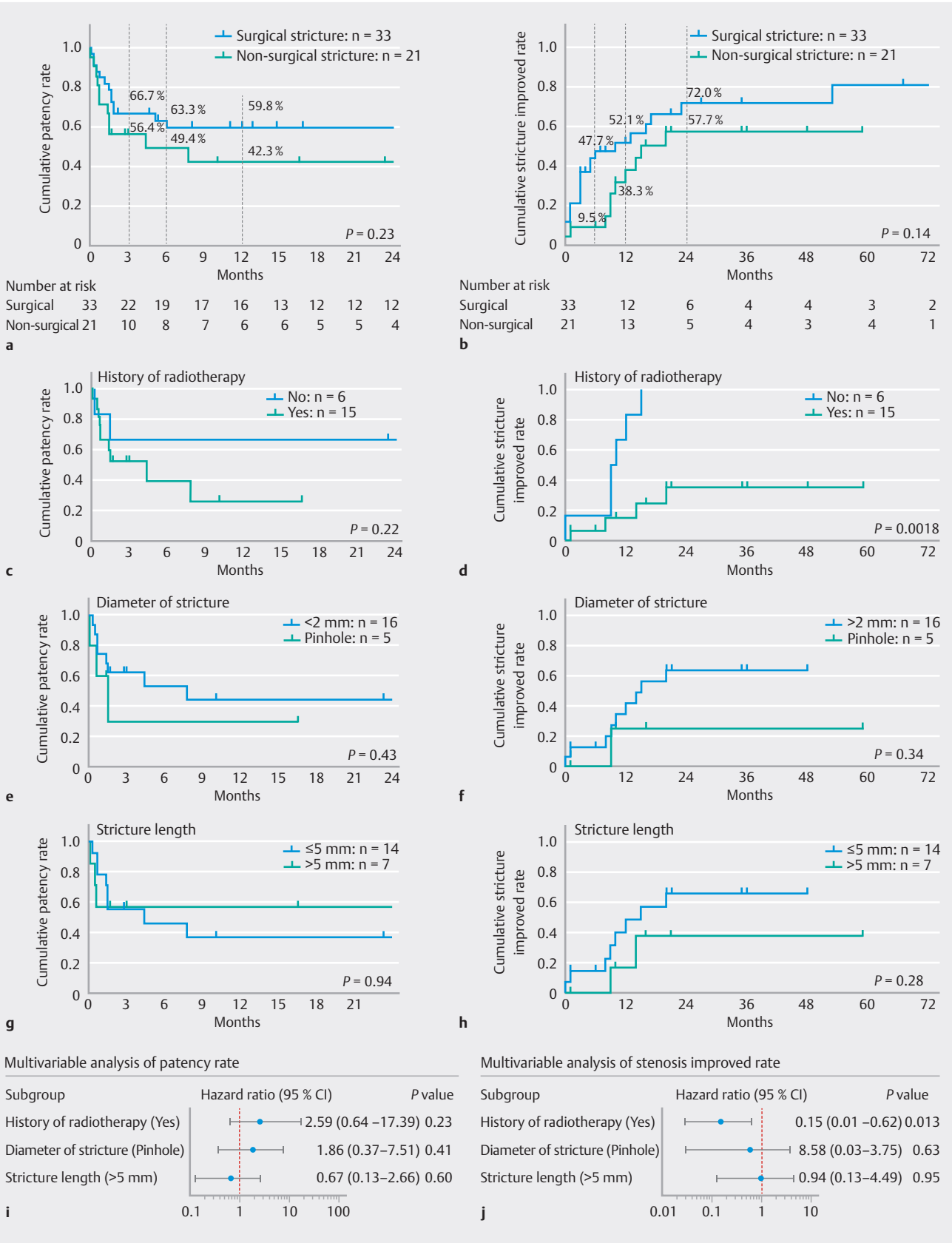
re-RIC, repeated radial incision and cutting.

Cumulative patency rate and cumulative stricture improved rate

During the median follow-up period of 22.3 months (range, 1.0–175.0), the cumulative patency rate, calculated as the patency period from the first RIC treatment to restenosis, was not statistically different between the nonsurgical stricture group and surgical stricture group ($P = 0.23$) (► **Fig. 3a**). The 3-, 6-, and 12-month patency rates in the nonsurgical stricture group

were 56.4%, 49.4%, and 42.3%, respectively. In contrast, the 3-, 6-, and 12-month patency rates in the surgical stricture group were 66.7%, 63.3%, and 59.8%, respectively.

The cumulative rate of improvement in stricture, calculated as the period from the first RIC treatment to achieving stricture improvement that made further EBD unnecessary, also was not statistically different between the nonsurgical stricture group and surgical stricture group ($P = 0.14$) (► **Fig. 3b**). The 6-, 12-, and 24-month stricture improvement rates in the nonsurgical



► **Fig. 3** Cumulative patency rates and stricture improved rates after first radial incision and cutting. **a, c, e, g** Cumulative patency rates. **b, d, f, h** Cumulative stricture improved rates. **a, b** Nonsurgical stricture group vs. surgical stricture group. **c, d, e, f, g, h, i, j** Subgroup analysis of the nonsurgical stricture group. **c, d** History of radiation therapy to esophagus. **e, f** Diameter of stricture. **g, h** Stricture length. **i, j** Relationship between the effect of the subgroups on patency and stricture improved rates.

► **Table 3** Safety profiles for radial incision and cutting.

| | All | Nonsurgical stricture | Surgical stricture | P value |
|---------------------------------|---------------|-----------------------|--------------------|---------|
| | n = 54 | n = 21 | n = 33 | |
| Procedure time, median (range) | 21 | 22 min (6–62) | 20 min (4–90) | 0.53 |
| Adverse event (CTCAE grade 1 <) | 2 (3.7) | 0 (0%) | 2 (6.1%) | 0.52 |
| Perforation of the esophagus | 2 | 0 | 2 | |
| Hospitalization period | 5 days (4–40) | 5 days (4–40) | 6 days (4–29) | 0.46 |

CTCAE, Common Terminology Criteria for Adverse Events v5.0.

stricture group were 9.5%, 38.3%, and 57.7%, respectively. In contrast, the 6-, 12-, and 24-month stricture improvement rates in the surgical stricture group were 47.7%, 52.1%, and 72.0%, respectively. None of the patients who achieved stricture improvement came to the hospital again because of stricture symptoms during the follow-up period.

To identify poor prognostic factors in the nonsurgical stricture group, further analysis was performed according to the history of radiation therapy to the esophagus (► Fig. 3c and ► Fig. 3d), stricture diameter (► Fig. 3e and ► Fig. 3f), and stricture length (► Fig. 3g and ► Fig. 3h). The cumulative stricture improvement rate was significantly lower in patients with a history of radiation therapy ($P = 0.0018$) (► Fig. 3d). In addition, a multivariate analysis of the subgroups in the nonsurgical stricture group was performed to compare hazard ratios (► Fig. 3i and ► Fig. 3j). A history of radiation therapy was an independent risk factor for resistance to stricture improvement ($P = 0.013$) (► Fig. 3j).

Safety evaluation for RIC

► Table 3 shows details of the safety profile for RIC. Median procedure time was 22 minutes (range, 6–62) in the nonsurgical stricture group and 20 minutes (range, 4–90) in the surgical stricture group ($P = 0.53$). RIC was performed on all hospitalized patients. The median hospitalization period was 5 days (range, 4–40) and 6 days (range, 4–29), respectively ($P = 0.46$). No CTCAE Grade 2 or higher AEs were observed in the nonsurgical stricture group. On the other hand, pinhole perforation was observed in two patients in the surgical stricture group ($P = 0.52$). These perforations were completely closed with conservative follow-up using intravenous antibiotics and fasting. In both cases, it was difficult to determine the direction of the incision during RIC because of the high degree of stenosis.

Discussion

Benign esophageal stricture is sometimes difficult to improve even with repeated EBD [15, 16, 17]. RIC has been investigated for surgical esophageal stricture and its efficacy and safety have been clarified, and it has become one of the minimally invasive treatment options for refractory benign esophageal stricture [8, 18, 19]. Surgical strictures occur at the anastomosis site after surgery, where the narrowing is typically sutured in a ro-

bust state. In contrast, nonsurgical strictures often result from radiation or inflammation, where the affected tissue is more fragile and the healing process may differ. Therefore, it is essential to investigate the safety and efficacy of RIC specifically for nonsurgical strictures.

In this study, the frequency of DS improvement over time and re-RIC intervention in the nonsurgical stricture group were no different from those in the surgical stricture group. There was no difference between the two groups in either the cumulative patency rate, which measures the time to restenosis, or the cumulative stenosis improvement rate, which measures the time until EBD is no longer required. No major complications were observed in the nonsurgical stricture group. These results indicate that RIC for nonsurgical refractory benign esophageal stricture is not inferior to surgical refractory benign esophageal stricture and might be considered as an effective and safe treatment option.

Because repeated EBD and frequent hospital visits reduce patient quality of life, the ultimate goal is to achieve improvement to the point where EBD is no longer necessary. Therefore, we defined “stricture improvement” as improvement to the point where EBD is no longer necessary as a new endpoint in this study. A recent study showed that re-RIC can be safely performed and is effective in the very short term. However, results at 3 and 6 months after re-RIC were not favorable [20]. In our study, 57.7% of patients no longer required EBD at 2 years despite a much lower cumulative stricture improvement rate of 9.5% at 6 months after first RIC in the nonsurgical group. This suggests that the long-term treatment strategy combining EBD and re-RIC is effective and frees about half or more of the patients in the nonsurgical stricture group from periodic EBD.

Because the effects of radiotherapy and the form of stricture may be prognostic factors, an exploratory analysis was performed in the nonsurgical stricture group, although the number of patients was small. A history of radiation therapy significantly lowers the cumulative stricture improvement rate and was an independent poor prognostic factor in multivariate analysis. One possibility is that tissue regeneration and wound healing processes after radiation therapy might differ from normal and limit the effectiveness of RIC and EBD [21, 22]. This population may have to establish the usefulness of long-time combination therapy with EBD and re-RIC. Therefore, it would be important to confirm the efficacy of RIC in patients with

nonsurgical refractory benign esophageal stricture after radiation therapy using a nationwide real-world survey and further prospective study.

This study has some limitations. First, it was a single-center retrospective study with a small number of patients. Second, strict evaluation of the diameter of stricture and stricture length over time after each treatment was difficult. In addition to distance and length, DS improvement, cumulative patency rate, and cumulative stricture improvement rate were also useful to evaluate the efficacy of RIC in this study. Third, although the patients followed a defined treatment strategy for refractory esophageal stricture, variations in the timing of re-RIC and repeat EBD may have affected the outcomes. Fourth, the improvement in dysphagia was the result of combination treatment with RIC, repeated EBD, and triamcinolone acetonide, and it is unclear which modality was most helpful.

Conclusions

In conclusion, RIC for nonsurgical refractory benign esophageal stricture could be an effective and safe treatment option. Some patients in the nonsurgical stricture group may have a favorable outcome if they continue to receive the combination of RIC and EBD.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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