

Efficacy and safety of repeated endoscopic radial incision and cutting procedure for benign esophageal stricture




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ABSTRACT

Background and study aims: Radial incision and cutting (RIC) is indicated for refractory benign esophageal strictures after curative treatment for esophageal cancer and has shown favorable short-term outcomes. However, re-stricture after RIC may occur in the long term, and RIC is performed repeatedly in such cases, but the efficacy and safety of repeated RIC are unclear. Therefore, we aimed to demonstrate the efficacy and safety of the repeated RIC for refractory benign esophageal strictures after surgical and non-surgical treatment.

Patients and methods: Between April 2008 and September 2019, we enrolled patients who were treated with the first RIC for benign esophageal strictures. The RIC was indicated for the refractory stricture and repeatedly performed for re-refractory esophageal stricture after RIC. We retrospectively evaluated the 6-month refractory stricture-free rate, and adverse events (AEs) in the first RIC and repeated RICs.

Results: Forty-six patients (39 men, 7 women; median age, 71 years, range 49–85) were included. RIC was performed once in 24 patients (non-repeated RIC group) and two or more times in 22 patients (repeated RIC group). In all patients, the 6-month refractory stricture-free rate after the first RIC were 42.3%. In the repeated RIC group, the 6-month refractory stricture-free rate after the first and repeated RICs were 18.2% vs 18.2%, respectively. No AEs were noted.

Conclusions: Repeated RIC could be effective in the short-term and safe even for patients with refractory benign esophageal stricture after the first RIC. However, it cannot be considered curative treatment for refractory stricture because of poor long-term results.

Introduction

Esophageal cancer is one of the most common causes of cancer-related death worldwide [1]. Surgery is the standard treatment for patients with esophageal cancer, and chemoradiotherapy (CRT) and endoscopic submucosal dissection (ESD) are also performed as nonsurgical treatments. However, benign

esophageal stricture is a well-known complication of these treatments [2–4]. Dysphagia due to stricture can reduce a patient's quality of life even if the esophageal cancer is cured. The standard treatment for esophageal stricture is endoscopic balloon dilation (EBD) or bougie dilation [5]. However, few strictures are relieved after the first EBD or bougie dilatation procedure, and most patients need more EBD [5].

Recently, radial incision and cutting (RIC), in which radial incisions are made with an insulated-tip (IT) knife, followed by cutting away the fibrotic tissue between these incisions, has been indicated for refractory esophageal strictures, which requires more than six sessions of EBD[5], and RIC has shown favorable outcomes [6–10]. Muto et al compared RIC with EBD for refractory esophageal stricture after surgery and found that the 6-month patency rate was significantly better after RIC than after EBD (65.3% vs. 19.8%) [6]. However, RIC seemed to offer only short-term relief, with a limited effect after a single session. Half of the patients required RIC repeatedly in a retrospective study [6]. UK guidelines on esophageal dilatation state that the outcomes of incision therapy are best for short strictures (<1.5 cm), and longer strictures may initially respond [11], but most will require repeated RIC, which may be less effective than the first RIC and may increase the number of adverse events (AEs). However, there have been no reports on the efficacy and safety of the repeated RIC. In this retrospective study, we aimed to clarify the efficacy and safety of the repeated RIC for refractory esophageal stricture.

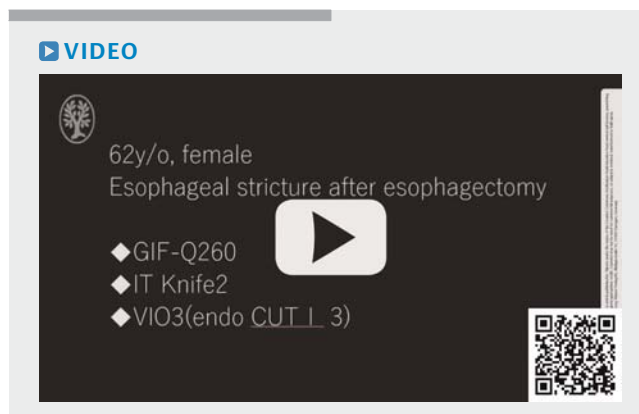
Patients and methods

Patients

Fifty-seven patients were treated with first RIC for stricture after treatment for esophageal cancer between April 2008 and September 2019 at our institution. The indications for the first RIC were when all of the following were met: (1) presence of refractory esophageal stricture or close to its condition with patient's request; and (2) confirmation of cure after esophageal cancer treatments such as CRT, ESD, surgery, or any combinations of these modalities. A stricture was defined as refractory when an ordinary-sized endoscope could not pass through the esophagus despite repeated EBD on more than six occasions within 6 months. RIC was not indicated for refractory long esophageal stricture (≥ 5 cm) after nonsurgical treatments due to the technical difficulty. The following were excluded from the study: (1) patients who were treated with RIC in order to perform endoscopic resection for other esophageal cancer on the anal side of the stricture; and (2) patients who could not be followed up for more than 6 months.

RIC procedure

The RIC procedure was performed as described previously (►Video 1) [7]. The patients received pethidine hydrochloride and/or midazolam immediately before the start of the RIC procedure. All RIC procedures were performed with an IT diathermic knife (KD-610L, IT knife/IT knife-2, Olympus, Tokyo, Japan) using ordinary-sized endoscopes (GIF-Q260, Q260J, or H290; Olympus) by expert endoscopists who had performed more than 100 cases of esophageal ESD. The RIC procedure was as follows: (1) the stricture area was incised radially using an IT knife; (2) an imaginary line that connects the esophageal lumen on the oral side and the lumen on the anal side was assumed; (3) a vertical incision was performed radially to the stricture along this line; (4) the incision area was sliced off; (5) the surface of the tight fibrotic area was shaved with a short-pronged



► Video 1 Presenting a video of the RIC procedure for esophageal stricture after esophagectomy.

blade of the IT knife; (6) the lumen was scraped with biopsy forceps as needed; (7) steps three to six were repeated; and (8) we confirmed that an ordinary-sized endoscope could pass through the stricture site; we used a thinner endoscope (XP260, XP260N, or XP240; Olympus) in the case of severe stricture. In addition, steroid (triamcinolone acetonide basically 50 mg) was injected into the stricture site immediately after RIC, mainly in cases with the long stricture at the discretion of the endoscopist although there were no clear criteria. The same method was performed for the repeated RIC. RIC procedures were basically performed at outpatient clinic. The patients rested at recovery room for 2 hours after the RIC procedure, and they were allowed to drink water after rest. And they were also allowed food intake at 4 hours after the RIC procedure.

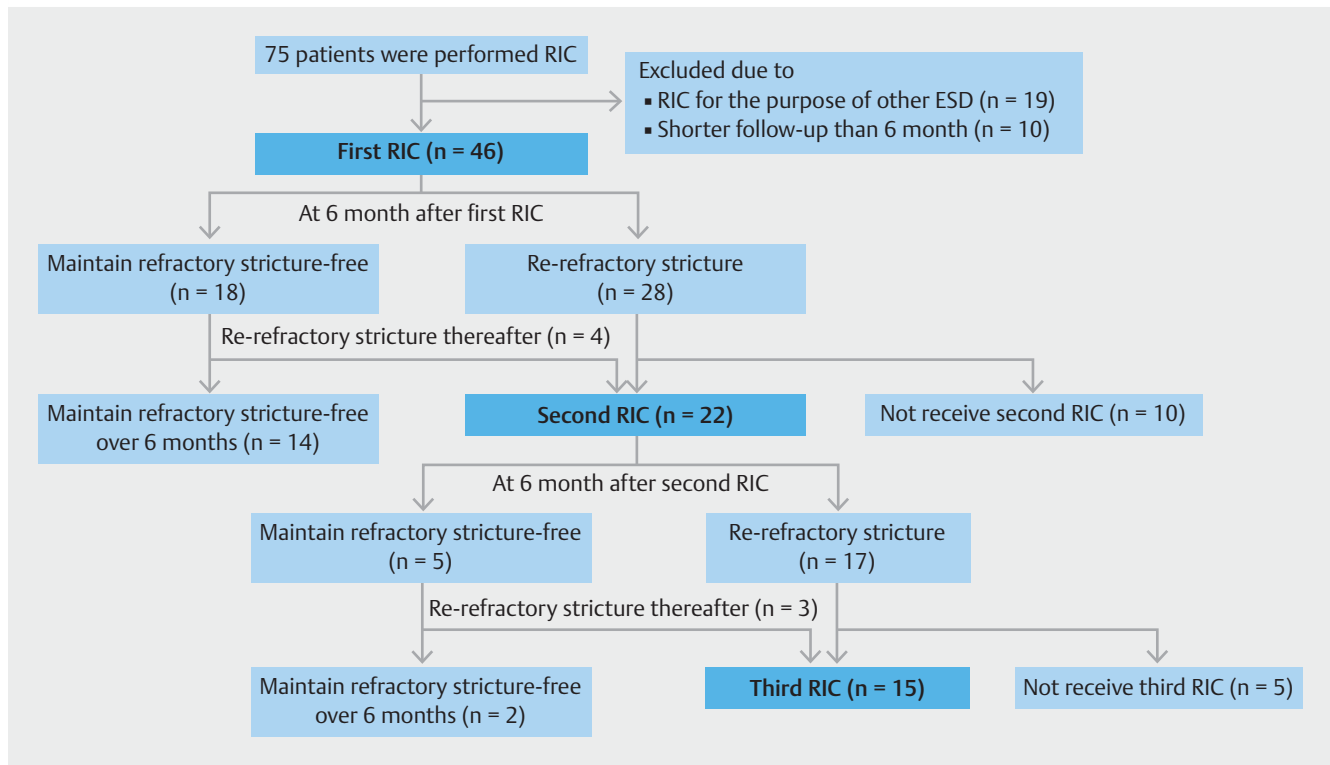
Follow-up

We performed endoscopic examination to evaluate for stricture within 2 to 4 weeks after the first RIC. EBD was performed when patients had recurrent symptoms of dysphagia or presence of esophageal stricture, and repeated approximately every 2 to 4 weeks according to the effect of the EBD and patient's symptoms until the symptoms disappeared or stricture improved. However, we did not perform with EBD and postponed if the ulcer after RIC remained. We also performed a repeated RIC when refractory stricture occurred after the first RIC or when patients had close to its condition and strongly requested for further improvement of discomfort during food intake, and we regarded the both conditions as re-refractory stricture.

Outcomes

In this study, the outcomes were 3-month refractory stricture-free (RSF) rate, 6-month RSF rate, and AEs. These outcomes were evaluated and compared between the second RIC in the repeated RIC group (group consisting of patients who repeated RIC) and the first RIC in all patients and the repeated RIC group. In addition, these outcomes were evaluated according to the cause of stricture (surgical group) vs. ESD group and CRT group.

The RSF rate was defined as period from the date of RIC to that of the first event of re-refractory stricture (when an ordin-



► Fig. 1 Study flowchart.

ary-sized endoscope could not pass through the esophagus despite repeated EBD more than six times and/or a repeated RIC), and patients without events were censored at the last date of contact for living patients. AEs were defined as: (1) perforation; and (2) bleeding requiring blood transfusion.

Statistical analysis

The 3- and 6-month RSF rates were estimated with the Kaplan-Meier method and compared by the aim log-rank test. $P < 0.05$ was considered to indicate statistical significance. All statistical analyses were performed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan, a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).

Ethical considerations

This was a single-center, retrospective study, and the protocol was approved by the Institutional Review Board of the National Cancer Center (2017–434). All data were collected from medical records. All procedures were performed after written informed consent was obtained from all the patients.

Results

Baseline patient characteristics

Of 75 patients who underwent the first RIC, 29 were excluded because of receiving RIC for the purpose of performing ESD on the anal side of the stricture ($n = 19$) and short follow-up ($n = 10$). Finally, 46 patients were enrolled (► Fig. 1).

As shown in ► Table 1, there were 39 male patients (84.8%), with a median age of 71 years (range, 49–85). The causes of stricture were esophagectomy in 31 (67.4%), ESD in eight (17.4%), and CRT in seven patients (15.2%). Forty-three patients underwent a median of eight (range, 1–77) EBD sessions before the first RIC. The reasons for performing RIC were the presence of refractory esophageal stricture in 30 (65.2%) and close to its condition with patient request in 16 patients (34.8%). Most of the patients who requested RIC had three or more prior EBD sessions before first RIC.

Efficacy and safety of first RIC

As shown in ► Table 2, an ordinary-sized endoscope could not pass through the stricture site immediately after the first RIC in 11 patients (23.9%) because of severe stricture, but a thin endoscope could pass. Steroid injection was administered immediately after the first RIC in 17 patients (37.0%). No AEs occurred after the first RIC. No bleeding with transfusion and requiring endoscopic hemostasis occurred after the first RIC.

As shown in ► Fig. 1, 18 patients remained RSF for 6 months after the first RIC with/without subsequent repeated EBD, and another 28 patients had a re-refractory stricture after the first RIC, which did not improve with repeated EBD. The 3- and 6-month RSF rate after the first RIC were 71.7 and 42.3% (► Fig. 2). Thereafter, of 18 patients with RSF at 6 months, four had a re-refractory stricture and received a second RIC, while the other 14 patients remained RSF. Of 28 patients with re-refractory stricture within 6 months, 18 received a second RIC, and the other 10 patients continued repeated EBD without receiving a third RIC.

► **Table 1** Background characteristics of patients.

Characteristics	Total (n = 46)	Repeated RIC group (n = 22)
Sex (%)		
▪ Male	39 (84.8%)	20 (90.9%)
▪ Female	7 (15.2%)	2 (9.1%)
Age (year), median (range)	71 (49–85)	71(60–80)
Stricture location (%)		
▪ Ce-Ut	7 (15.2%)	4 (18.2%)
▪ Mt-Lt	8 (17.4%)	3 (13.6%)
▪ Anastomosis	31 (67.4%)	15 (68.2%)
Cause of stricture (%)		
▪ Esophagectomy	31 (67.4%)	15 (68.2%)
▪ ESD	8 (17.4%)	3 (13.6%)
▪ CRT	7 (15.2%)	4 (18.2%)
No. prior EBD sessions before first RIC, times, median (range)	8 (1–77) ¹	8 (1–21) ¹
No. EBD sessions between first and second RIC, times, median (range)		5 (0–43)
Duration of repeated EBD between first and second RIC, days, median (range)		106 (12–1436)
Reason for performing RIC		
▪ Refractory esophageal stricture	30 (65.2%)	11 (50.0%)
▪ Patient request	16 (34.8%)	11 (50.0%)

ESD, endoscopic submucosal dissection; CRT, chemoradiation therapy; EBD, endoscopic balloon dilation; RIC, radial incision and cutting.

¹ Excluding data from three patients who were referred to our hospital for RIC after performing EBD at previous hospital.

► **Table 2** Details of first and second RIC.

	First RIC in all patients (n = 46)	Second RIC in repeated RIC group (n = 22)	P value
Procedure time, min, mean±SD	18.4 ± 13.8 ¹	17.4 ± 13.3 ²	0.81
Number of an ordinary sized endoscope could not pass immediate after RIC (%)	11 (23.9%)	6 (27.3%)	0.77
3-month RSF rate	71.7%	50.5%	<0.01
6-month RSF rate	42.3%	18.2%	<0.01
Steroid injection after RIC (%)	17 (37.0%)	5 (22.7%)	0.28
Adverse events			
▪ Perforation (%)	0 (0%)	0 (0%)	n.a.
▪ Bleeding (%)	0 (0%)	0 (0%)	n.a.

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

¹ Excluding the missing data in 12 patients..

² Excluding missing data in four patients

ing a second RIC. Finally, 22 patients (47.8%) received a second RIC (the repeated RIC group), and 14 (30.4%) maintained RSF after first RIC.

Repeated RIC group

As shown in ► **Table 1**, the causes of stricture in the repeated RIC group were esophagectomy in 15 (68.2%), ESD in three (13.6%), and CRT in four patients (18.2%). A median of eight

sessions (range, 1–21) of repeated EBD were performed before the first RIC. In addition, a median of five sessions of repeated EBD (range, 0–43) were performed between the first and second RIC. The second RIC was performed after a median of 106 days (range, 12–1436) from the first RIC. The reasons for performing second RIC were presence of refractory esophageal stricture in 11 (50.0%) and close to its condition with patient's request in 11 patients (50.0%). Most of these request patients had three or more prior EBD before first RIC.

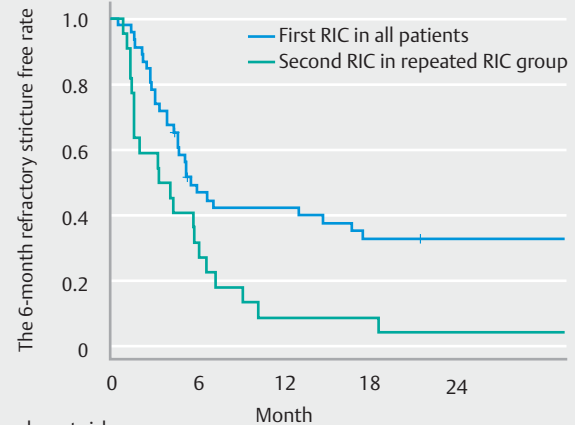
As shown in ► **Table 2**, the mean procedure time of the second RIC was 17.4 minutes, which was almost the same as that of first RIC in all patients (18.4 minutes, $P=0.81$). In six patients (27.3%), an ordinary-sized endoscope could not pass through the stricture site immediately after the second RIC, although a thin endoscope could pass. Steroid injection immediately after the second RIC was administered in five patients (22.7%). There were no AEs after the second RIC. No bleeding with transfusion and requiring endoscopic hemostasis occurred after the second RIC.

As shown in ► **Fig. 1**, five patients remained RSF for 6 months after the second RIC with/without subsequent repeated EBD, while the other 17 patients had a re-refractory stricture after the second RIC, which did not improve with repeated EBD. In the repeated RIC group, the 3- and 6-month RSF rate after the first was 45.5 and 18.2%, and those after second RIC procedures was 50.5 and 18.2% ($P=0.77$), respectively (► **Fig. 3**). On the other hand, the 3- and 6-month RSF rates were significantly lower after the second RIC in the repeated RIC group than after the first RIC in all patients ($P=0.005$) (► **Fig. 2**). According to the cause of stricture, the 3- and 6-month RSF rates after first RIC in the repeated RIC group were 33.3% and 33.3% in ESD group, 50.0% and 25.0% in the CRT group, and 46.7% and 13.3% in the surgical group (► **Fig. 4**). Similarly, the 3- and 6-month RSF rate after second RIC were not reached and not reached in the ESD group, 50.0% and not reached CRT group, and 60.0% and 33.3% in the surgical group (► **Fig. 5**).

Moreover, of five patients with RSF at 6 months, three had a re-refractory stricture and received a third RIC, and the other two patients remained RSF. Of the 17 patients with re-refractory stricture within 6 months, 12 received a third RIC, and the other five patients continued repeated EBD without receiving a third RIC. Finally, 9.1% of patients (2/22) with a second RIC showed improvements in the refractory stricture only with the second RIC, and 68.2% (15/22) received a third RIC (► **Fig. 1**). In total, 13 patients received RIC five times, and five received RIC 10 times. No AEs occurred in any of the 311 RIC procedures.

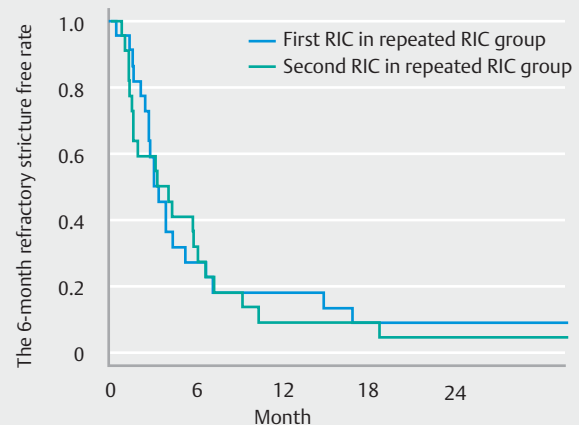
Discussion

This study shows that repeated RIC for refractory esophageal stricture was safe and relatively effective in the short-term as the first RIC, but because of poor long-term results, it cannot be considered as the curative treatment of refractory benign esophageal stricture. The 3- and 6-month RSF rates were significantly lower after the first and second RIC in the repeated RIC group than after the first RIC in all patients, but the rates were similar after the first and second RIC in the repeated RIC



Number at risk					
First RIC in all patients	46	20	18	14	13
Second RIC in repeated RIC group	22	7	2	2	1

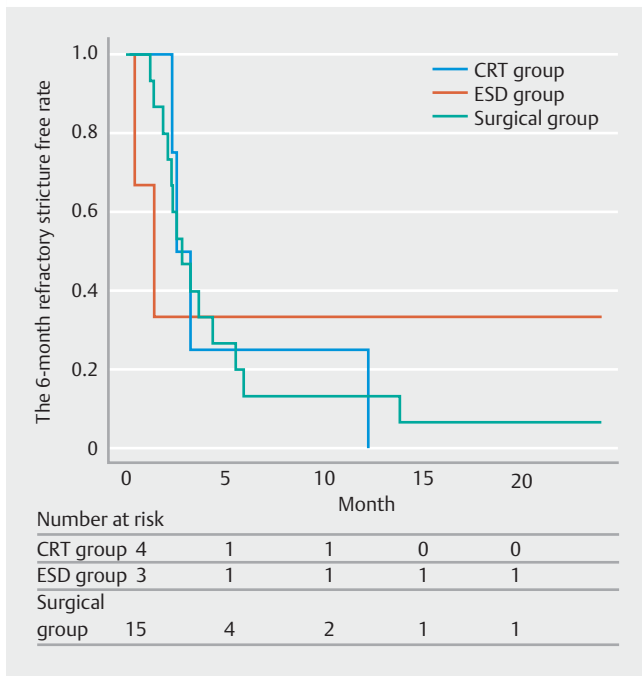
► **Fig. 2** Comparison between the first RIC in all patients and the second RIC in the repeated RIC group. The 6-month RSF rate was significantly better after the first RIC in all patients than after the second RIC in the repeated RIC group (42.3% vs 18.2%, $P=0.0051$).



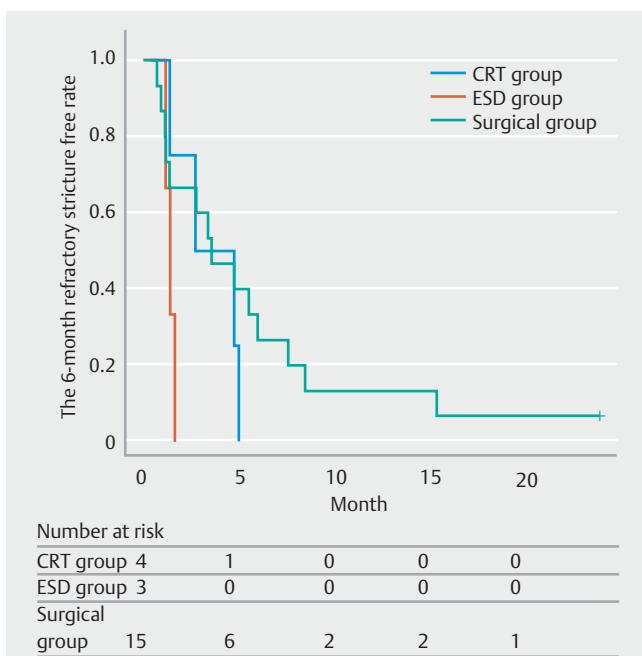
Number at risk					
First RIC in repeated RIC group	22	6	4	2	2
Second RIC in repeated RIC group	22	7	2	2	1

► **Fig. 3** Comparison between the first and second RICs in the repeated RIC group. The 6-month RSF rate after the first RIC was the same as that after second RICs in the repeated RIC group (18.2% vs 18.2%, $P=0.77$).

group. There have been some reports about the efficacy of RIC for refractory esophageal stricture, but the number of patients has been small. Muto et al. conducted a retrospective cohort study comparing RIC and EBD for refractory esophagogastric anastomotic stricture [6]. Although dysphagia improved within a month after RIC in 93.8% patients, it decreased to 63.0% at 6



► **Fig. 4** Comparison between ESD group and CRT group and surgical group in the first RIC in the repeated RIC group. The 6-month RSF rate was similar between ESD group (33.3%) and CRT group (25.0%) and surgical group (13.3%) ($P=0.992$).



► **Fig. 5** Comparison between ESD group and CRT group and surgical group in the second RIC in the repeated RIC group. The 6-month RSF rate was similar between ESD group (NA) and CRT group (NA) and surgical group (33.3%) ($P=0.132$).

months after RIC [6]. In addition, Yano et al. reported in a case series that dysphagia in all eight patients notably improved dysphagia symptoms after RIC without any major complications [10]. However, the long-term efficacy was unfavorable, and re-intervention was required in 75% within 6 months after RIC, and long strictures (>2 cm) tended to be refractory. From these reports, RIC is regarded as a more effective method in the short-term for refractory esophageal stricture compared to EBD, but its long-term efficacy is unsatisfactory.

In this study, while approximately 30% of patients who underwent the first RIC could overcome the refractory stricture, only 9.1% were RSF after the second RIC. Few cases of refractory esophageal stricture that could not be released by the first RIC were improved by the second RIC, and the RIC was repeated. However, the efficacy of the repeated RIC was similar to that of the first RIC for patients who required a repeated RIC in terms of the 3- and 6-month RSF rates, and this seemed to indicate that the efficacy of RIC did not decrease even with repetitions. These results suggest that the repeated RIC could be an option for treating refractory esophageal strictures resistant to first RIC in daily practice, as the repeated RIC might reduce the number of procedures compared to EBD. In addition, repeated RIC could avoid surgical resection to relieve refractory strictures. Thus, repeated RIC may also have an important role as maintenance and not definitive treatment, even in cases of first RIC failure.

However, the effectiveness of repeated RIC is limited, and new treatments for refractory esophageal stricture have been developed to date. Temporary placement of a self-expandable stent is weakly recommended in the European Society of Gastrointestinal Endoscopy guidelines as a definitive treatment for failed EBD and RIC for refractory stricture failure [12]. Among the various types of expandable stents, such as self-expandable plastic stents, self-expandable metallic stents, and biodegradable (BD) stents, BD stents may be more effective and tolerable because they require less reintervention and no need for removal unlike the other stents [13, 14]. We previously reported that BD stents were effective and tolerable for refractory esophageal strictures; however, their long-term efficacy was limited in the prospective trial [15]. The dysphagia-free survival rates after BD stent placement at 12 and 24 weeks were 83.3% and 16.7%, respectively, and patients in this BD stent study had a history of severe stricture with a median of 23 EBDs (range, 3–182) sessions and 4.5 RICs (range, 1–32). Because of the imbalance in intervention history for the stricture before enrollment in the present and BD stent study, it was difficult to judge the superiority of the efficacy in each modality for refractory cases after the first RIC. Although we did not experience any AEs with repeated RIC, the placement of BD stents led to severe AEs in some cases. Based on the balance between efficacy and safety for each treatment, BD stents should be considered as maintenance therapy, especially when repeated RIC has failed; however, both treatments may be inadequate for long-term maintenance. In the future, it is hoped that new treatments for refractory esophageal stricture will be developed as an alternative to repeated RIC and BD stents.

This study had some limitations. First, because it was retrospective, the severity of stricture before RIC and the therapeutic effect of RIC could not be correlated. In this study, there were various causes of stricture such as esophagectomy, ESD, and CRT. In addition, because the follow-up timing and methods, such as the presence and frequency of EBD and the type of endoscope, and the reason and timing for selecting RIC varied among patients, the severity of stricture before RIC also seemed to vary. And we had not assessed the degree of stricture, such as the length and diameter of the stricture. In terms of the therapeutic effect of RIC, there were some cases in which an ordinary scope could not pass through the stricture site after RIC and patients that did not receive local steroid injection after RIC, which could have caused a non-uniform therapeutic effect. For the same reason, the clinical factors associated with the efficacy of RIC could not be analyzed. The second limitation of this study was its single-center design. The RIC method has not yet been standardized globally. As such, the same efficacy and safety noted in this study may not be achievable in other institutions. Currently, a multicenter randomized controlled study (JCOG1207; jRCTs031180177) that aims to compare EBD followed by local steroid and RIC followed by local steroid for refractory anastomotic stricture after esophagectomy is being conducted [16], and its result should partially address the limitations of the first RIC. As the demand for stricture treatment after a first RIC increases, a multicenter prospective study will be needed to overcome these limitations in the future.

Conclusions

Repeated RIC for refractory esophageal stricture could be safe and relatively effective in the short term as the first RIC, but because of poor long-term results, it cannot be considered as curative treatment for refractory benign esophageal stricture even if repeated. Thus, new treatment methods that can relieve dysphagia in the long term are desired for such cases.

Acknowledgments

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Competing interests

The authors declare that they have no conflict of interest.

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