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Utility of modified endoscopic radial incision and selective cutting combined with short-term stenting for refractory stricture in patients undergoing endoscopic submucosal dissection of superficial esophageal carcinoma

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Abstract

Background: Refractory esophageal stricture is the common complication of extensive endoscopic submucosal dissection (ESD), without satisfactory endoscopic treatment strategies. We evaluated the efficacy, safety, and long-term patency of the modified endoscopic radial incision and selective cutting combined with short-term stenting (RISC-STS) for the treatment of refractory esophageal stenosis.

Methods: This was a retrospective study. Patients diagnosed with refractory esophageal stricture from June 2016 to June 2023 were enrolled. Efficacy, safety, and risk factors for dysphagia after RISC-STS operation were assessed.

Results: Compared with clinical symptoms before RISC-STS, there was no significant improvement in the times of stricture recurred ($p = 0.75$). However, the narrowest diameter of esophageal stenosis was significantly larger after RISC-STS treatment ($p = 0.04$). Corresponding dysphagia scores after RISC-STS were obviously lowered according to the Mellow–Pinkas grading scale ($p = 0.002$). More cases ((14 (60.87%) vs 5 (21.74%)) received valid symptom-relief periods after RISC-STS ($p = 0.0004$). The complications of RISC-STS include perforation (4.35%), fever (4.35%), and pain (30.43%). Univariate Cox analysis suggested that resection length >7 cm of scar tissue was a risk factor for refractory dysphagia after RISC-STS.

Conclusion: The present study revealed that RISC-STS is an effective and safe technique for refractory esophageal stricture with lower restenosis, higher valid symptom-relief rate, and fewer complications.

Keywords: refractory esophageal stricture, superficial esophagus carcinoma, the modified endoscopic radial incision and selective cutting combined with short-term stenting

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Introduction

Esophageal carcinoma is the eighth most common cancer worldwide and is associated with poor prognosis and survival rates.[1] In the early stage of esophageal cancer, superficial esophagus carcinoma (SEC), the 5-year survival rate can reach more than 85%.[2] Endoscopic submucosal dissection (ESD) is widely used in patients diagnosed with SEC with the advantage of less invasion, maintaining the integrity of digestive tract structure, and complete resection of lesions.[2,3]

However, refractory esophageal stricture is the common complication of extensive ESD (⩾3/4 of the luminal circumference).[4–6] Refractory esophageal stricture refers to endoscopic dilatation once every 2 weeks for five consecutive times, but standard endoscopy still fails to pass the stenosis site or re-diagnosed with esophageal stenosis.[7] Esophageal stenosis is mainly manifested as dysphagia and swallowing pain, as well as a series of complications such as malnutrition, aspiration, pain, and respiratory failure, which seriously affect the life quality of patients.[8] Therefore, formulating a reasonable treatment strategy to relieve esophageal stenosis is vital.

Endoscopic treatment strategies involve endoscopic dilation, endoscopic drug injection, esophageal stenting, regenerative medicine, and endoscopic incision (EI).[9] Endoscopic dilation treatment[10,11] includes Savary bougie dilation and balloon dilatation[12] with the main complications of bleeding, perforation, chest pain, and bacteremia. Endoscopic drug injections include steroid[6,13] and mitomycin.[14] At present, steroid injection has become the main prevention method for esophageal stenosis after ESD for superficial esophageal cancer,[15] however the long-term efficacy is not satisfactory. Esophageal stenting[16–18] could continuously dilate the stenosis segment, whereas esophageal stenting is not recommended as the first-line treatment due to more potential complications such as displacement, difficult removal, retrosternal pain, bleeding, perforation, and aspiration pneumonia. Regenerative medicine[19–21] is mainly used for the prevention of esophageal stenosis, which is based on the principle that transplanted materials and tissues could repair and replace the damaged tissues, maintaining their physiological function and accelerating the healing of tissues. However, most of the research regarding regenerative medicine is still in the animal model stage, and more clinical studies are needed to confirm the safety and efficacy.[20]

EI[22–27] refers to the utility of a needle knife, an IT knife, or endoscope scissors to cut through the narrow section to achieve the purpose of expansion. EI was first reported by Simmons and Baron[28] in refractory benign esophageal stricture (RBES) patients. In 2020, our department reported the efficacy of the modified endoscopic radial incision and cutting method (M-RIC) for patients with refractory esophageal stenosis.[25] It was shown that M-RIC could extend the restenosis time to 110 days with a lower restenosis rate compared to the dilation group.[25]

Based on our previous study, in this research, we conducted the modified endoscopic radial incision and selective cutting combined with short-term stenting (RISC-STS) to alleviate esophageal stenosis, and the efficacy, safety, and long-term patency of RISC-STS were evaluated.

Methods

Ethical approval

The study was approved by the Clinical Research Ethics Committee of Zhongda Hospital Southeast University (approval no. 2024ZDSYLL042-P01). All the procedures of our study followed the Declaration of Helsinki.

Patients

From June 2016 to June 2023, 23 patients diagnosed with refractory esophageal stenosis were treated with RISC-STS at our institution and were retrospectively enrolled in the study. The inclusion criteria: (1) All the patients had been diagnosed with refractory esophageal stricture following ESD for superficial esophageal carcinoma, based on their symptoms, endoscopy, and pathology results. (2) Patients underwent endoscopic dilatation once every 2 weeks for five consecutive times, but standard endoscopy still could not pass the stenosis site or re-diagnosed with esophageal stenosis. Exclusion criteria: (1) Diagnosis of malignant esophageal strictures, metastasis, or esophageal fistula. (2) Diagnosis of severe cardiopulmonary dysfunction or coagulation dysfunction and inability to tolerate the endoscopic operation. (3) Systemic disease requiring oral intake of steroid medication.

Treatment

RISC-STS procedure

All patients were operated under general anesthesia by an experienced endoscopist. For patients who receiving RISC-STS, submucosal injection with a mixture of 100 ml saline, 1% indigo carmine, and 1% epinephrine was administered 2 cm above the stenosis segment. The scar tissue was cut along the lamina propria surface as far as possible by an I-type hybrid knife (ERBE, Tübingen,

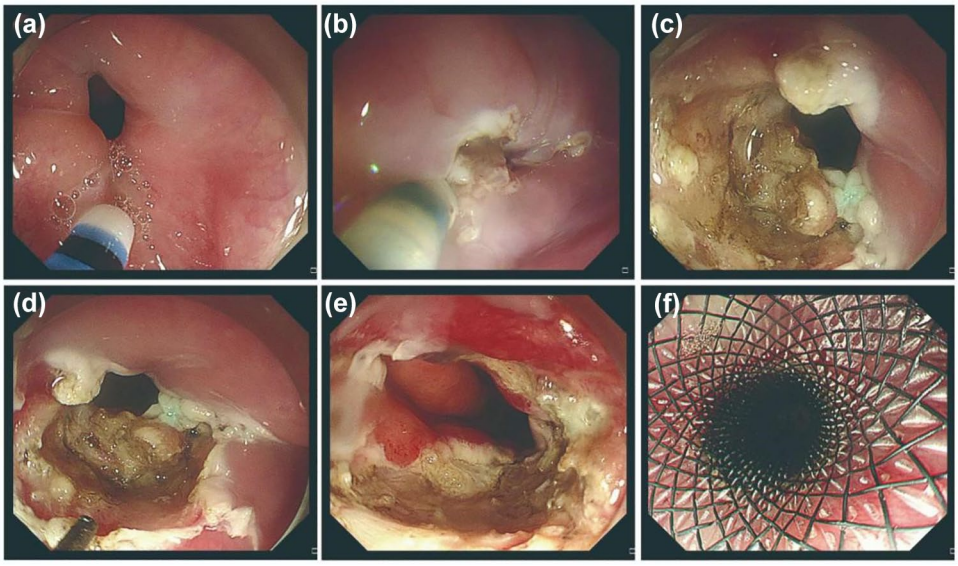

Figure 1. RISC-STS procedure. (a) Esophageal lumen was too narrow for endoscopy to pass. (b–e) Radial incision was performed and scar tissue was cut along the surface of the lamina propria. (f) Stents placement. The esophageal lumen was significantly enlarged.
RISC-STS, radial incision, and selective cutting combined with short-term stenting.

Germany) or dual knife (KD-650L; Olympus, Tokyo, Japan) or IT knife (KD-611L; Olympus, Tokyo, Japan). If the esophageal lumen was too narrow to pass through, a dilation or radial incision was made to remove the scar around the lumen until the endoscopy could pass through the stenosis. Bleeding vessels were coagulated by hemostatic forceps (FD-410LR; Olympus). Stents (Nanjing Microtech, Nanjing, China) was routinely placed (Figure 1). Triamcinolone acetonide submucosal injection and fibrin adhesives spray were applied according to the patient's condition. All patients were fasted for at least 24 h after surgery, with acid suppression, hemostasis, and anti-infection treatment. Biopsies of the strictures were obtained to confirm that they were benign. One month later after RISC-STS, the stents would be removed. Technical success was defined as a 9.9 mm endoscope that was able to pass through the original stenosis segment. Clinical success was defined as the patients being able to take oral fluids or semi-fluids after surgery.

Stent placement procedure

The patient was supine and left anterior oblique at 45°. Then, a 0.035-inch guide wire was inserted into the esophagus from the mouth until the tip of the guide wire entered the stomach cavity. Then, the stent (Nanjing Microtech) with double recyclable wire and transporter pass through the guide wire, releasing the stent in the narrow segment.

Follow-up

Endoscopy was performed at 1, 6, 12, 24, and 36 months after treatment. Additional visiting was needed when patients felt difficulty swallowing. During follow-up, further treatment was required when the patients had recurrent dysphagia and endoscopy was unable to pass through the stenosis. The patency time was recorded as the interval between the success of endoscopic therapy techniques and endoscopic confirmation of stenosis recurrence. All patients were followed via clinical recorder or telephone.

Statistical analysis

The statistical analysis was performed using SPSS 26 (IBM, Armonk, New York, USA). Quantitative statistics, including age, follow-up time, expansion time, operating time, longitudinal resection length, and resection depth were expressed as median and interquartile (IQR). Qualitative statistical results are expressed in frequency. Quantitative variables were compared

Table 1. Baseline characteristics.

Variables	*N* (%)/*M* (range)
Sex (male/female)	11/12
Age, median (IQR), years	64 (58–67.5)
Location, *n* (%)	
Upper esophagus	5 (21.7)
Middle esophagus	11 (47.8)
Lower esophagus	7 (30.4)
Circumferential extent, *n* (%)	
⩽1/2	11 (47.8)
>1/2	12 (52.2)
Specimen size, median (IQR), cm^2	1 (0.2–1.4)
Pathological type, *n* (%)	
High-grade neoplasia	10 (43.5)
Squamous carcinoma	11 (47.8)
Adenocarcinoma	2 (8.7)
Infiltration depth, *n* (%)	
M1	4 (17.4)
M2	2 (8.7)
M3	4 (17.4)
SM1	13 (56.5)
R0 resection, *n* (%)	23 (100)
Comorbidities, *n* (%)	
Hypertension	3 (13.0)
Diabetes	2 (8.7)
Smoking history, *n* (%)	5 (21.7)
Drinking history, *n* (%)	5 (21.7)

IQR, interquartile range.

by *t*-tests. Qualitative variables were compared using Chi-squared or Fisher's exact tests. Univariate logistic regression analyses were used to determine the risk factors for re-dysphagia after RISC-STS. *p*-Value <0.05 was considered significant.

Results

Patients characteristics

Baseline demographics and indications for patients were summarized in Table 1. The male-to-female ratio was 11:12 and the median age was 64 (IQR, 58–67.5) years. The cases with esophageal neoplasms located at the lower, middle, and upper esophagus were 5 (21.74%), 11 (47.83%), and 7 (30.43%), respectively. The circumferential range of lesions in 12 (52.17%) patients was greater than 1/2 of the esophageal circumference, and the median area of the lesion was 1 (IQR, 0.2–1.35) cm^2. Postoperative pathological confirmed 10 (43.48%) cases with high-grade neoplasia, 11 (47.83%) cases with squamous cell carcinoma, and 2 (8.70%) cases with adenocarcinoma. The percentage of M1 or M3 lesions was all 4 cases (17.39%); however, 2 cases (8.70%) with M2 and 13 cases (56.52%) with SM1 lesions. The lesions of all the cases were removed completely. For all patients, hypertension (three cases, 13.04%) and diabetes (two cases, 8.70%) were the most common basic diseases. In addition, a history of smoking or drinking was found in five cases, respectively.

Efficacy of RISC-STS

Comparison of clinical outcomes between pre- and post-RISC-STS treatment were listed in Table 2. Technical success was achieved in 23 (100%) patients. The follow-up period pre- and post-RISC-STS were 9 (IQR, 4.5–54) months and 36 (IQR, 24–39) months, respectively. During the median of 36 months after RISC-STS, stricture recurred in 14 cases (60.87%), and 9 cases remained stricture-free. Compared with clinical symptoms before RISC-STS, no significant improvement was observed in the times of stricture recurred ($p = 0.75$). However, the narrowest diameter of esophageal stenosis was significantly larger after RISC-STS treatment ($p = 0.04$). Meanwhile, corresponding dysphagia scores after RISC-STS were obviously lowered according to the Mellow–Pinkas grading scale ($p = 0.002$). As for the treatments for stricture recurred, without RISC-STS, high proportion of patients experienced the combination therapy of balloon dilation and stent implantation ($p = 0.037$). In addition, these patients also experienced more times of dilation ($p = 0.006$). We defined a continuous 2-month interval of dysphagia-free, consistent with Mellow–Pinkas score ⩽1

Table 2. Comparison of clinical outcomes between pre- and post-RISC-STS treatment.

Variables	Pre	Post	*p*-Value
Period of follow-up, median (IQR), months	9 (4.5–54)	36 (24–39)	
Esophageal restenosis, *n* (%)	23 (100)	14 (60.9)	<0.01
Restenosis times, *n* (%)			
⩽4	17 (73.9)	11 (78.6)	0.75
>4	6 (26.1)	3 (28.6)	
Diameter of stricture, *n* (%)			
⩽2 mm	12 (52.2)	0 (0)	0.04
>2 mm and ⩽5 mm	3 (13.0)	5 (35.7)	
>5 mm	8 (34.8)	9 (64.3)	
Mellow–Pinkas, *n* (%)			
0	0 (0)	10 (43.5)	0.002
1	4 (17.4)	6 (26.1)	
2	12 (52.2)	5 (21.7)	
3	7 (30.4)	2 (8.7)	
4	0 (0)	0 (0)	
Expansion method, *n* (%)			
Balloon dilation	10 (43.5)	11 (78.6)	0.037
Balloon dilation + stent placement	13 (56.5)	3 (2.1)	
Expansion times, median (IQR)	3 (2–4.5)	1 (0–2.5)	0.006
Number of patients who acquired valid symptom relief, *n* (%)	5 (21.7)	17 (73.9)	0.0004

Mellow–Pinkas: grade 0: no symptom of dysphagia; grade 1: dysphagia to solid food; grade 2: dysphagia with ingestion of semisolid food; grade 3: dysphagia to liquids; grade 4: aphagia.
IQR, interquartile range; RISC-STS, radial incision, and selective cutting combined with short-term stenting.

as a valid symptom-relief period (VSP). More cases ((14 (60.87%) vs 5 (21.74%)) received VSP after RISC-STS ($p = 0.0004$).

Safety of RISC-STS

Table 3 shows the details of the RISC-STS. The median procedure time was 35 min (30–60), and the median hospital stay was 7 days (6–8). Overall, the median longitudinal resection length was 5 cm (4–8) and resection depth was 0.5 cm (0.3–0.5). KD-650L knife, KD-611L knife, and hybrid knife were used during the operation. Based on the resection range, six types of stents were selected for implantation. Thirteen cases (56.5%) were given intralesional steroid injections. The incidence of intra-operation perforation and fever were both 4.4%, and seven patients (30.4%) required the administration of painkillers, and the pain was relieved by the medicine within a few days.

Risk factors for dysphagia after RISC-STS operation

Regarding the tendency of optimal improvement in dysphagia symptoms, univariate Cox

Table 3. Safety of RISC-STS.

Variables	*N* (%)/*M* (range)
Operating time, median (IQR), min	35 (30–60)
Hospital days, median (IQR), d	7 (6–8)
Muscular injury, *n* (%)	2 (8.70)
Longitudinal resection length, median (IQR), cm	5 (4–8)
Resection depth, median (IQR), cm	0.5 (0.3–0.5)
Knife type, *n* (%)	
KD-650L knife	4 (17.4)
KD-650L knife + KD-611L knife	2 (8.7)
Hybrid knife	17 (73.9)
Stent type, *n* (%)	
16 mm × 100 mm	4 (17.4)
16 mm × 120 mm	5 (21.7)
18 mm × 100 mm	4 (17.4)
18 mm × 120 mm	5 (21.7)
20 mm × 100 mm	2 (8.7)
20 mm × 120 mm	3 (13.0)
Combined with steroid, *n* (%)	13 (56.5)
RISC-STS related complication, *n* (%)	
Perforation	1 (4.4)
High fever ⩾38°C	1 (4.4)
Pain requiring painkiller drug	7 (30.4)

RISC-STS, radial incision, and selective cutting combined with short-term stenting.

analysis was used to determine the factors affecting the Mellow–Pinkas score. After RISC-STS, 17 patients (73.9%) obtained a decrease and 6 patients (26.1%) experienced an increase or no change in Mellow–Pinkas score. The baseline data are shown in Table 4 and risk factors, such as sex, age, esophageal cancer characters, stenosis features, and RISC-STS procedure were analyzed. Univariate Cox analysis suggested that resection length >7 cm of scar tissue was a risk factor for refractory dysphagia after RISC-STS.

Discussion

With the widely popularization of ESD for superficial esophageal carcinoma, post-resection refractory stricture draws more attention to the negative effect on quality of life and financial expenditure.[7] To manage the refractory stricture, various endoscopic treatments have been studied. EI, which was conducted with a needle knife, IT knife, or endoscopic scissors to incise the fibrotic section of stenosis.[22,23,28,29] EI was first reported for relieving refractory esophageal anastomotic stenosis by Simmons and Baron.[28] In their study, eight patients with refractory esophageal stricture were followed up after treatment of RBES from 90 to 140 days, and all the symptoms of dysphagia were relieved.[28] Subsequently, endoscopic radial incision was proved to lower restenosis rates and longer recurrence-free survival compared with endoscopic balloon dilation.[22] Radial incision and cutting method (RIC) was based on radial incision, followed by cutting away the fibrotic tissue between the incisions. RIC was applied in refractory stricture after nonsurgical treatment of esophageal cancer, which showed that dysphagia in all the patients was relieved significantly without major complications.[23]

M-RIC has been conducted in our department since 2016[25] and the technical success rate could reach 100%. M-RIC aimed to cut off scar tissue along the surface of the lamina propria as much as possible. Compared with dilation, M-RIC was demonstrated with lower restenosis incidence and longer restenosis time. In addition, we found that stenosis length ⩾5 cm is a risk factor for restenosis and oral prednisone could alleviate restenosis after M-RIC.[25] Based on the previous study, we made a few changes to the M-RIC procedure to introduce a new method, RISC-STS, for the treatment of refractory esophageal stricture. In detail, after the incisions and excision of the scar, a short-time stent placement was conducted. In this retrospective study, the efficacy, safety, and long-term patency of RISC-STS were investigated in patients with refractory esophageal stricture after radical resection of esophageal cancer. We found that RISC-STS could enlarge the diameter of esophageal stenosis, and decrease dysphagia scores, and the times of dilation. In addition, more cases received VSP after RISC-STS.

Interestingly, when analyzed by univariate Cox regression, the longer longitudinal resection length of the mucosal defect resulted in a

Table 4. Risk factors for dysphagia after RISC-STS operation.

Variables	Effective ($n=17$)	Ineffective ($n=6$)	OR (95% CI)	p-Value
Demographic characteristics				
Sex, female, *n* (%)	9 (52.9)	3 (50)	1.125 (0.175–7.243)	0.901
Age >60 years, *n* (%)	13 (76.5)	1 (16.7)	0.237 (0.461–22.927)	0.237
Infiltration depth, *n* (%)				
M1/M2/M3	5 (29.4)	6 (100)	Ref	
SM1	1 (70.6)	0 (0)	12.00 (1.103–130.58)	0.051
Circumferential range, *n* (%)				
⩽1/2	7 (41.2)	4 (66.7)	Ref	
>1/2	10 (58.8)	2 (33.3)	2.857 (0.405–20.141)	0.292
Stenosis before RISC-STS				
Stricture location, *n* (%)				
Upper esophagus	13 (76.5)	3 (50)	Ref	
Middle or lower esophagus	4 (23.5)	3 (50)	0.308 (0.044–2.171)	0.237
Stricture diameter, *n* (%)				
⩽2 mm	8 (47.1)	4 (66.7)	Ref	
>2 mm	9 (52.9)	2 (33.3)	2.250 (0.321–15.756)	0.414
RISC-STS procedure				
Operation time, *n* (%)				
⩽60 min	15 (88.2)	4 (66.7)	Ref	
>60 min	2 (11.8)	2 (33.3)	0.267 (0.028–2.526)	0.249
Resection length, *n* (%)				
⩽7 cm	15 (88.2)	2 (33.3)	Ref	
>7 cm	2 (11.8)	4 (66.7)	0.067 (0.007–0.632)	0.018
Combined with steroid, *n* (%)	11 (64.7)	2 (33.3)	1.400 (0.199–9.869)	0.736

CI, confidence interval; OR, odds ratio; RISC-STS, radial incision and selective cutting combined with short-term stenting.

higher refractory incidence as previous studies reported.[30,31] A study including 507 cases[32] suggested long segment strictures being a risk factor of refractory stricture, and Vladimir Andreevski[33] proposed stricture >2 cm responded less to dilation, while our previous study found patients with stricture length ⩾5 cm tend to suffer from a higher risk of esophageal restenosis after M-RIC.[25] In this study, we also found that the longitudinal resection length of scar tissue (>7 cm) was a risk factor for refractory dysphagia after RISC-STS.

There are still several limitations in our study. Firstly, for this retrospective research, the median period of follow-up was 9 and 36 months pre and post-RISC-STS, respectively, which may lead to

limited information. Secondly, due to the single-center trial with small size of cases, multi-center prospective studies with larger sample sizes and longer follow-ups were needed to eliminate potential bias. Overall, RISC-STS might reduce the severity of recurring stenosis and improve the prognosis of patients with superficial esophageal carcinoma after ESD, and it appears to be a feasible and safe treatment for refractory stricture.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Zhongda Hospital Southeast University (approval no. 2024ZDSYLL069-P01). All study procedures adhered to the Declaration of Helsinki. The ethics committee waived the requirement for obtaining informed consent from the patients owing to the retrospective nature of the study.

Consent for publication

Not applicable.

Author contributions

Lu Chen: Conceptualization; Investigation; Writing – original draft.

Xiajiao Tang: Data curation; Software.

Jingjing Jiang: Formal analysis; Validation.

XiaoChun Yin: Methodology; Resources.

Yuxin Wang: Data curation; Formal analysis.

Mingyue Li: Project administration; Writing – review & editing.

Ruihua Shi: Conceptualization; Data curation; Writing – review & editing.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

The data used and analyzed during the study are available from the lead author and the corresponding authors on reasonable request.

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