Prospective Cohort Study

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A novel self-inflatable balloon for treating refractory benign esophageal strictures: a prospective, single-arm, multicenter study

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Background and Aim: Current treatments for refractory benign esophageal strictures (BESs) often take several years and have poor effects. The authors propose a novel method of self-help inflatable balloon (SHIB) and evaluate its efficacy and safety.

Methods: A prospective, multicenter study was conducted from January 2019 to March 2022. All enrolled patients were diagnosed with refractory BESs and received SHIB. The primary endpoint was the clinical success rate at 12 months after removing SHIB. The secondary endpoints were the number of days of placing SHIB, and changes from baseline in BMI and health-related quality of life at 1, 3, 6, and 12 months.

Results: The clinical success rate was 51.2% (21/41) with the median days of placing SHIB being 104.0 days (range: 62.0–134.5 days), which was higher in the endoscopic group compared to the caustic and surgery groups (63.3 vs. 28.6% vs. 0, $P = 0.025$). All patients (100%) showed significant improvement in dysphagia scores during placing SHIB. Although 20 patients (48.8%) experienced recurrent stricture, the median stricture length was decreased ($P < 0.001$) and the median intervention-free interval was prolonged ($P < 0.001$). In all patients, the mean BMI at and health-related quality of life at 1, 3, 6, and 12 months were significantly increased compared with baseline ($P < 0.05$). On multivariate analysis, stricture etiology and wearing time were independent predictors of recurrent stricture.

Conclusions: The SHIB has high efficacy and safety in treating refractory BESs of different origins, especially for endoscopic resection. Stricture etiology and wearing time were independent predictors of recurrent stricture.

Keywords: balloon, caustic, endoscopic submucosal dissection, esophageal stricture

Introduction

Benign esophageal strictures (BESs) are a problem commonly encountered by gastroenterologists in clinical practice, and may be induced by various causes, with extensive endoscopic resection, caustic, and anastomosis being the primary causes[1]. These strictures cause symptoms of progressive dysphagia, regurgitation, chest pain, and vomiting, which dramatically decrease the patient's quality of life[2]. As most of those strictures are cicatricial and fibrotic, the treatment has always been difficult. However, 30–40% of these patients show poor responses even after repeated rigorous dilation, and ultimately progressing to refractory BESs[3,4].

Refractory BESs are defined by a failure to pass a standard endoscopy after five successive dilation sessions[5]. Managing these patients is extremely challenging, and the current treatments include repeated endoscopic balloon dilation (EBD), corticosteroid injections, endoscopic incisional therapy (EIT), and temporary stent placement[6–9]. Therapies are expensive, time-consuming, of

HIGHLIGHTS

- Refractory benign esophageal strictures decrease patient quality of life.
- After a shorter treating period, self-help inflatable balloon has a high clinical success rate in treating refractory benign esophageal strictures of different origins, especially for endoscopic resection.
- All patients had significant improvement in dysphagia scores after wearing the self-help inflatable balloon.
- Stricture etiology and wearing time were independent predictor for recurrent stricture.

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limited long-term effectiveness, and impose a significant burden on both the patient and healthcare team. Despite repeated interventions, patients often still experience recurrent strictures and require nutritional support. The largest study of the natural history of refractory BESs revealed that the mean intervention-free interval was 3 months, and only 2.4 months after placing metal stents[10]. Thus, a new method for treating refractory BESs is urgently needed.

We previously reported a promising clinical result of using a self-help inflatable balloon (SHIB) to prevent stricture after esophageal circular endoscopic submucosal dissection (ESD). The stricture rate was reduced to 12.5%, far below that achieved using other methods[11,12]. Whether the novel method can be successfully used in the treatment of refractory BESs is not certain. Therefore, we conducted a prospective study to evaluate the efficacy and safety of SHIB for treating BESs.

Patients and methods

Patients

This study was a prospective, single-arm conducted at three tertiary referral centers. From January 2019 to March 2022, consecutive patients aged 18–80 years old diagnosed with refractory BESs and considered the SHIB method were enrolled in the study. The inclusion criteria were as follows: (1) the etiology of the BESs was anastomosis, caustic, or complete circular endoscopic resection; (2) the patient was able to master the process and skills of operating the SHIB by himself; (3) written informed consent to participation in the study was provided by the patient. The exclusion criteria were as follows: (1) received fewer than five endoscopic treatments before placing SHIB; (2) the etiologies of esophageal strictures were malignant tumors; (3) chronic steroid treatment had been administered; (4) esophageal fistula or perforation was detected in endoscopic view before the placement of SHIB ; (5) patient could not be followed up regularly or adequately.

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committees of all three participating hospitals. The prospective cohort study was registered with ResearchRegistry.com. The work was reported in accordance with the strengthening the reporting of cohort, cross-sectional and case–control studies in Surgery (STROCSS) criteria[13] (Supplemental Digital Content 1, http://links.lww.com/JS9/B723).

Description of the SHIB

The main components of the SHIB have been described previously in detail[12]. The maximum diameter of the balloon is 18 mm, which is smaller than the average esophageal diameter of 20 mm, thus increasing safety while maintaining efficacy. The validity length was 80 mm, which was longer than that of most stricture segments. A protective soft pipe was attached at the front of the device to avoid mucosal injury. To increase safety and convenience, air rather than water is pumped into the balloon. The detailed structure of the SHIB is shown in Figure 1.

The balloon needs to be operated effectively by the patients themselves at home, and therefore standardized training is required before self-dilation. The training included several stages, as described here. Firstly, detailed verbal directions on the dilation procedure, and also familiarization with the dilation equipment. Secondly, an instructional video that showed how to perform the balloon dilation was presented. Thirdly, emphasis was placed on the necessity of accurate position fixation, and instructions were provided on how to adjust the balloon's location based on the mark when migration occurred. Fourthly, two methods could be used to facilitate the identification of SHIB migration. One method involved the use of a scale on the tube, which was fixed on the nose. The second method was the use of a mark, such as a medical bandage with 2–3 mm in width wrapped around the tube in the proper location. Finally, during the process of self-dilation, some patients with severe stricture probably need to drug the tube fixed on the nose with some resistance, as the balloon was prone to migrate to the annual side.

Preliminary dilation strategies

For most patients, the procedures were scheduled in the outpatient department, unless short-term hospitalization was required after the endoscopy because of the patient's clinical conditions. Before placing the SHIB, traditional endoscopic treatment procedures for treating strictures were also needed. In the three centers, EBD and EIT were two widely used methods. The choice between the EBD and EIT procedures and the initial dilation diameter depended on the operator's preference.

Endoscopic placement procedures

Immediately following the final EBD or EIT, the balloon catheter with water-based lubricant applied was passed from the nose to the required location. The procedure was similar to inserting a stomach tube and could be performed successfully without the assistance of a guide wire. After confirming that the balloon was in the stricture location under endoscopic view, we fixed the catheter on the nose. It is also essential to confirm the location of the balloon before pumping air. A mark was also needed to ensure the correct location of the catheter.

Postoperative management and follow-up

A liquid diet was provided on the first day if no serious complications occurred during the operation. Patients followed a half-liquid diet for three days and gradually arrived at a general diet. Antibiotics were not required. Proton pump inhibitors were given orally until one week after removing SHIB.

On the second day post-ESD, the patient was instructed to pump 35 ml of air into the balloon 4–5 times a day for 15–20 min each time. All patients underwent endoscopic examination to confirm the position of the balloon and to monitor for the appearance of artificial ulcers at 1–2 weeks after the operation. Subsequently, the frequency of endoscopic review was reduced to every 3–4 weeks on an individualized basis, and patients were closely supervised and followed up via weekly phone calls. All the balloons were removed when the ulcers were almost healed. BMI, and health-related quality of life (HRQoL) estimated by the 36-item Short Form Health Survey questionnaire (SF-36) were obtained at 1, 3, 6, and 12 months after placing the SHIB. The patients were followed up with endoscopy scheduled at 2 weeks, 3, 6, and 12 months after removing the balloon and annually thereafter.

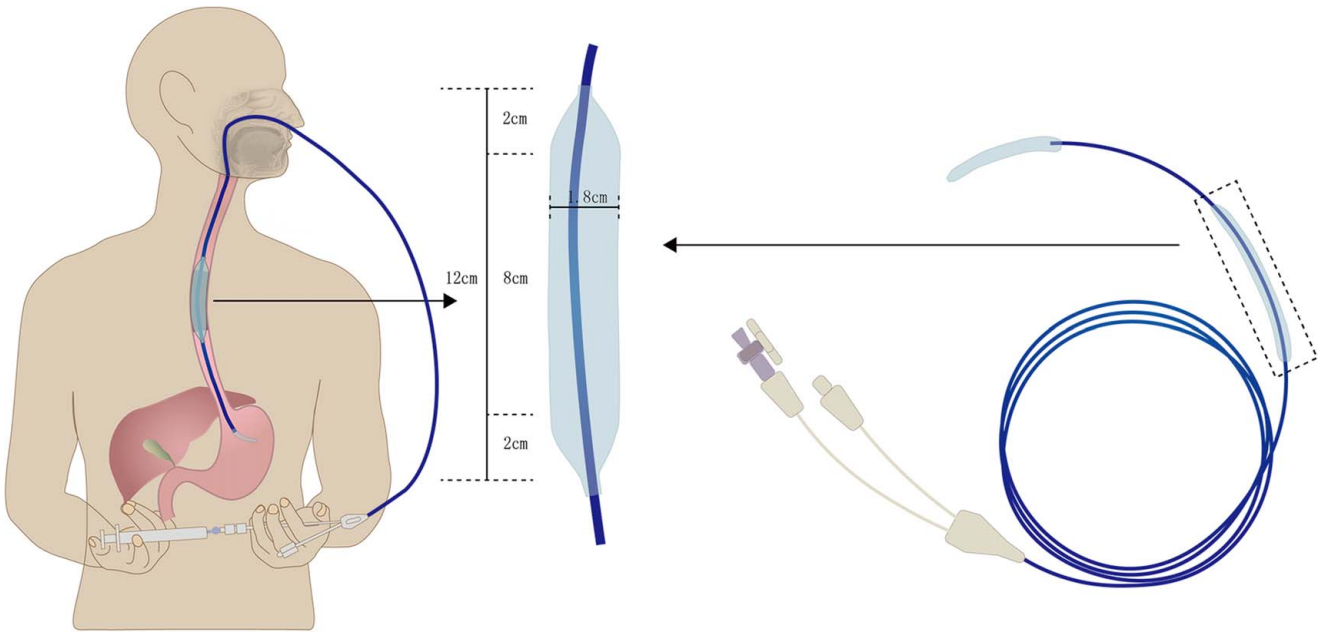

Figure 1. Diagram of the self-help inflatable balloon (SHIB). The novel balloon can be easily operated by the patient himself.

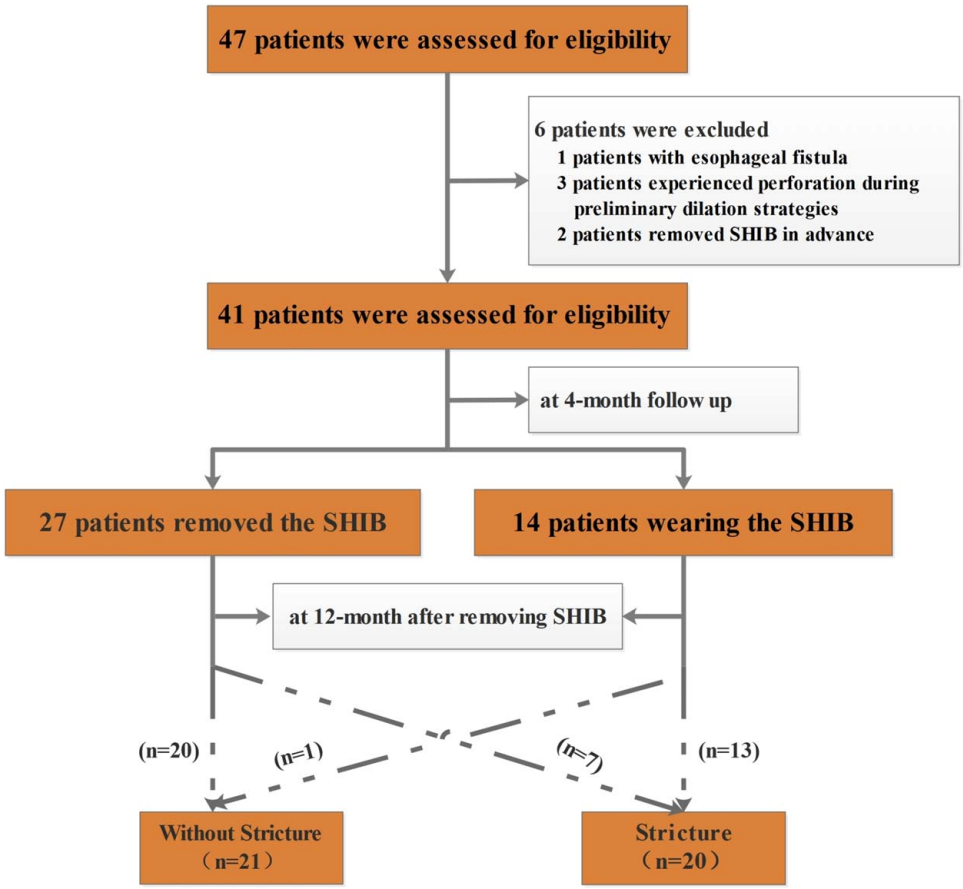

Figure 2. Flowchart of study enrollment and outcomes.

Table 1

Baseline characteristics, efficacy, and adverse events related to three groups.

	Total ($n=41$)	Endoscopic Group* ($n=30$)	Caustic Group† ($n=7$)	Surgery Group‡ ($n=4$)	*P*
Patient factor					
Age, years (mean ± SD, range)	56.6 ± 15.6	62.7 ± 10.1	31.4 ± 12.9	59.3 ± 10.5	< 0.001
Sex (male/female)	33/8	24/6	6/1	3/1	0.903
Tumor location, *n* (%)					< 0.001
Nonmultifocal	37 (90.2%)	30 (100.0%)	3 (42.9%)	4 (100.0%)	
Multifocal	4 (9.8%)	0 (0.0%)	4 (57.1%)	0 (0.0%)	
Median stricture length, *n* (%)					0.096[a]
≤ 2 cm	20 (48.8%)	16 (53.3%)	1 (14.3%)	3 (75.0%)	
> 2 cm	21 (51.2%)	14 (46.7%)	6 (85.7%)	1 (25.0%)	
Median stricture diameter, *n* (%)					0.247[a]
< 5 mm	25 (61.0%)	17 (56.7%)	5 (71.4%)	3 (75.0%)	
≥ 5 mm	16 (39.0%)	13 (43.3%)	2 (28.6%)	1 (25.0%)	
Mellow–Pinkas score, *n* (%)					0.415[a]
3/4	23/18	18/12	4/3	1/3	
BMI, kg/m^2	20.8 ± 3.3	21.3 ± 2.7	19.4 ± 4.2	18.8 ± 4.6	0.155
Treatment factors					
Dilation strategies, *n*/*n*					0.006[a]
EBD/RIC	24/17	22/8	1/6	1/3	
Time of wearing balloon, days (IQR)	104.0 (62.0–134.5)	94.0 (60.0–124.3)	124.0 (91.0–331.0)	130.5 (109.0–242.7)	0.057
Adverse events, *n* (%)					0.742
Perforation	0	0	0	0	
Delayed bleeding	0	0	0	0	
Throat pain	37 (90.2%)	27 (90.0%)	6 (85.7%)	4 (100.0%)	
Nose pain	32 (78.0%)	24 (80.0%)	5 (71.4%)	3 (75.0%)	
Postoperation factors					
Clinical success, *n* (%)	51.2% (21/41)	63.3% (19/30)	28.6% (2/7)	0.0% (0/4)	0.025
Time to restricture, days (IQR)	57.5 (29.5–73.3)	63.0 (42.0–96.0)	28.0 (11.0–63.0)	47.0 (28.7–63.7)	0.143
Follow-up, month, mean ± SD	33.6 ± 16.2	36.1 ± 16.7	29.1 ± 14.5	22.5 ± 11.1	0.101

*Stricture caused by extensive endoscopic resection.
†Stricture caused by caustic.
‡Stricture caused by surgery.
[a]Analysed using Fisher's exact test.
EBD, endoscopic balloon dilation; IQR, interquartile range; RIC, endoscopic incisional therapy.

Study endpoints and definitions

The primary endpoint was the incidence of clinical success after removing the SHIB. Clinical success was defined as patients could eat soft solids without recurrent stricture for at least 12 months after removing SHIB. Recurrent was defined as the recurrence of difficulty in deglutition (Mellow–Pinkas score ≥ 2) and/or inability to pass a standard endoscopy. The secondary endpoints were the number of days of placing SHIB, intervention-free interval, the improvement in dysphagia scores, change in BMI from baseline, and HRQoL at 1, 3, 6, and 12 months, and any other adverse events. The intervention-free interval was defined as the number of days from removing SHIB to the observation of recurrent stricture. Adverse events such as throat pain, nose pain, delayed bleeding, and perforation were recorded after placing SHIB. The Common Terminology Criteria for Adverse Incidents (CTCAE) version 4.0.10 and the Clavien–Dindo classification were used to evaluate and grade these events[14,15].

Statistical analysis

The data were statistically analyzed using SPSS version 25 (SPSS; IBM). Quantitative data were expressed as the means (SDs) or the medians (interquartile ranges). Continuous variables were compared using the Student's *t*-test or the Mann–Whitney *U*-test. Categorical variables were analyzed using the χ^2 test or Fisher's exact test. Potential risk factors for esophageal recurrent were identified by multivariate analysis using a Cox proportional hazards regression model, with forward stepping of variables with a significance level of $P < 0.05$ based on univariate analyses.

Results

Patient characteristics

Out of 47 patients considered receiving SHIB, one diagnosed with an esophageal fistula, three experienced perforation during preliminary dilation strategies, and two removed SHIB prematurely because of a diagnosis of esophageal or gastric cancer. Therefore, 41 patients (33 males and 8 females) with a mean age of 56.6 ± 15.6 years remained enrolled in the study (Fig. 2). Data on clinical characteristics, stricture etiology, tumor location, median stricture length, and median stricture diameter are presented in Table 1. Of these patients, 30 (80.5%) patients developed strictures after endoscopic resection, while seven (17.1%) and four (9.7%) patients were diagnosed after caustic and surgery, respectively. Four (9.8%) strictures caused by caustic were located in the multifocal esophagus. Twenty (48.8%) patients had strictures that were ≤ 2 cm in length, and 21 (51.2%) patients were > 2 cm in length. All patients completed follow-up visits according to the physician's requirements. No patient was lost in follow-up in our study.

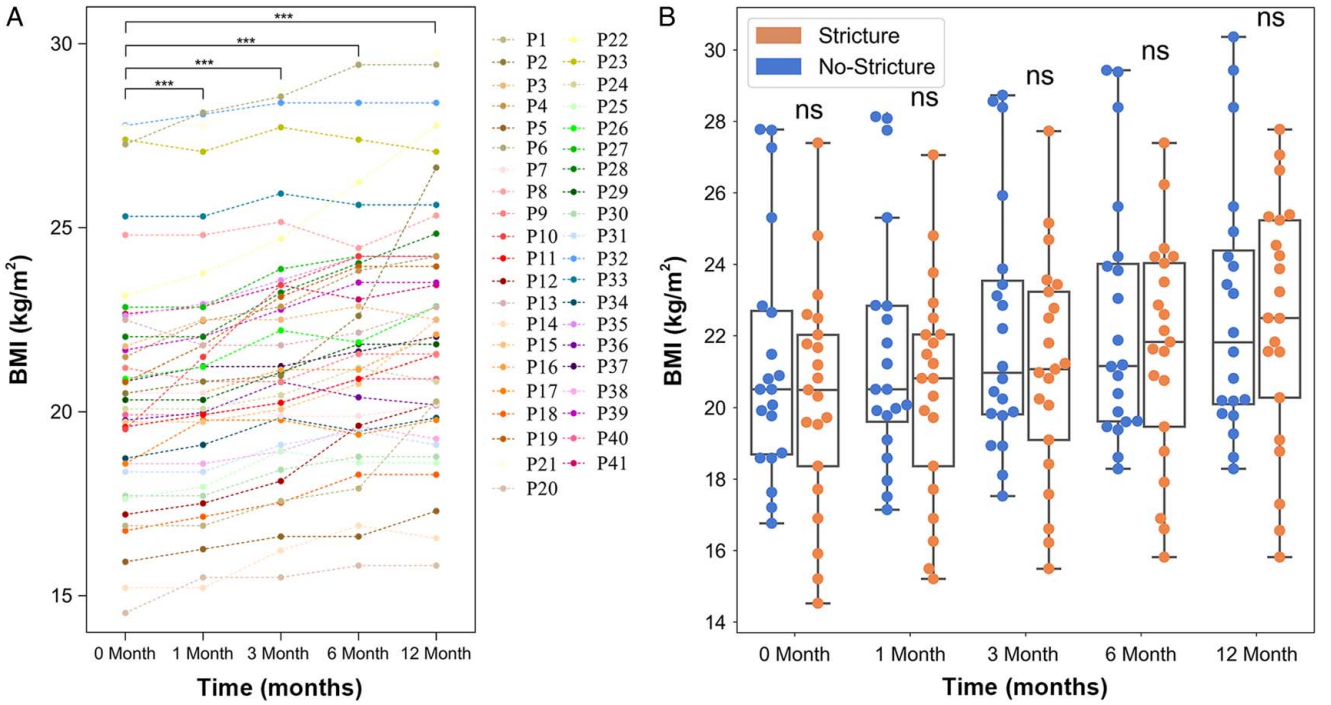

Figure 3. Outcomes of secondary efficacy endpoints. A, BMI at baseline and at 1, 3, 6, and 12 months of follow-up. ***$P < 0.001$. B, BMI in different groups of stricture and nonstricture at 1, 3, 6, and 12 months of follow-up. ns, No significance.

Effectiveness of SHIB

As shown in Table 1, stricture length and diameter were comparable in different groups. EBD and EIT were used in 24 (58.5%) and 17 (41.5%) patients, respectively, before the placement of SHIB. At the 4-month follow-up, 24 (58.5%) patients had already removed SHIB. The median time of wearing SHIB was 104.0 days (range: 62.0–134.5 days). The median time of wearing SHIB in the endoscopic group was less than in the other two groups, though no significant difference was detected ($P = 0.057$). During a median follow-up of 33.6 months, clinical success was achieved in 63.3% (19/30) of the patients in the endoscopic group, which was significantly higher than that of the other two groups (28.6% in the caustic group and 0% in the surgery group, $P = 0.025$). Nineteen patients (79.2%) who removed SHIB within 4 months did not experience recurrent stricture, compared to only 2 (9.5%) who removed SHIB >4 months. During the period of SHIB placement, dysphagia scores were significantly improved in 100% (41/41) of patients, which were classified into 0 or 1 point in the Mellow–Pinkas score. No endoscopic intervention was performed during the period. The median time from removing the balloon to recurrent stricture was 57.5 days (IQR: 27.0–75.5 days), and no significant differences were detected among the three groups.

The mean BMIs of patients at 1, 3, 6, and 12 months post-procedure were 21.04 ± 3.23 kg/m^2, 21.60 ± 3.30 kg/m^2, 22.00 ± 3.30 kg/m^2, and 22.57 ± 3.47 kg/m^2, respectively, and were significantly higher at 1, 3, 6, and 12 months compared with the baseline ($P < 0.001$ for all comparisons) (Fig. 3A). The increasing trend was more significant at 3 month, and slowing down at 6 and 12 months because of some patients experienced recurrent stricture. There were no differences in BMI between the stricture and no stricture groups or between the complete ($P > 0.05$ for all comparisons, Fig. 3B), implying all patients have significant nutrition improvement despite recurrent stricture. More detailed information is presented in Supplementary Table 1 (Supplemental Digital Content 2, http://links.lww.com/JS9/B724). Furthermore, the 36-item Short Form Health Survey at 1, 3, 6, and 12 months showed greater scores in the eight domains compared with the baseline ($P < 0.05$ for all comparisons, except 1 month in PF, Fig. 4), illustrating a significant improvement in HRQoL following the placement of SHIB.

Safety of SHIB

The adverse events that occurred during the placement of SHIB are presented in Table 1. The most common adverse events were throat pain and sore pain, which occurred in 90.2% (37/41) and 78.0% (32/41) of all patients, respectively, with pain scores of 2–3 on the visual analog scale. These two symptoms generally occurred 4–5 days after ESD and were gradually relieved by 2–3 weeks after ESD. All of the above adverse events were grade 1 or 2 according to CTCAE version 4.0.10, and were grade 1 according to the Clavien–Dindo classification. No patient in the study experienced perforation or delayed bleeding in the study. All potential complications are described in Supplementary Table 2 (Supplemental Digital Content 2, http://links.lww.com/JS9/B724).

A patient in the endoscopic group who had received nine sessions of EBD and three sessions of EIT before the placement of SHIB is shown in Figure 5. A patient in the caustic group who had received seven sessions of EBD and one session of esophageal metal stent before the placement of SHIB is shown in Figure 6.

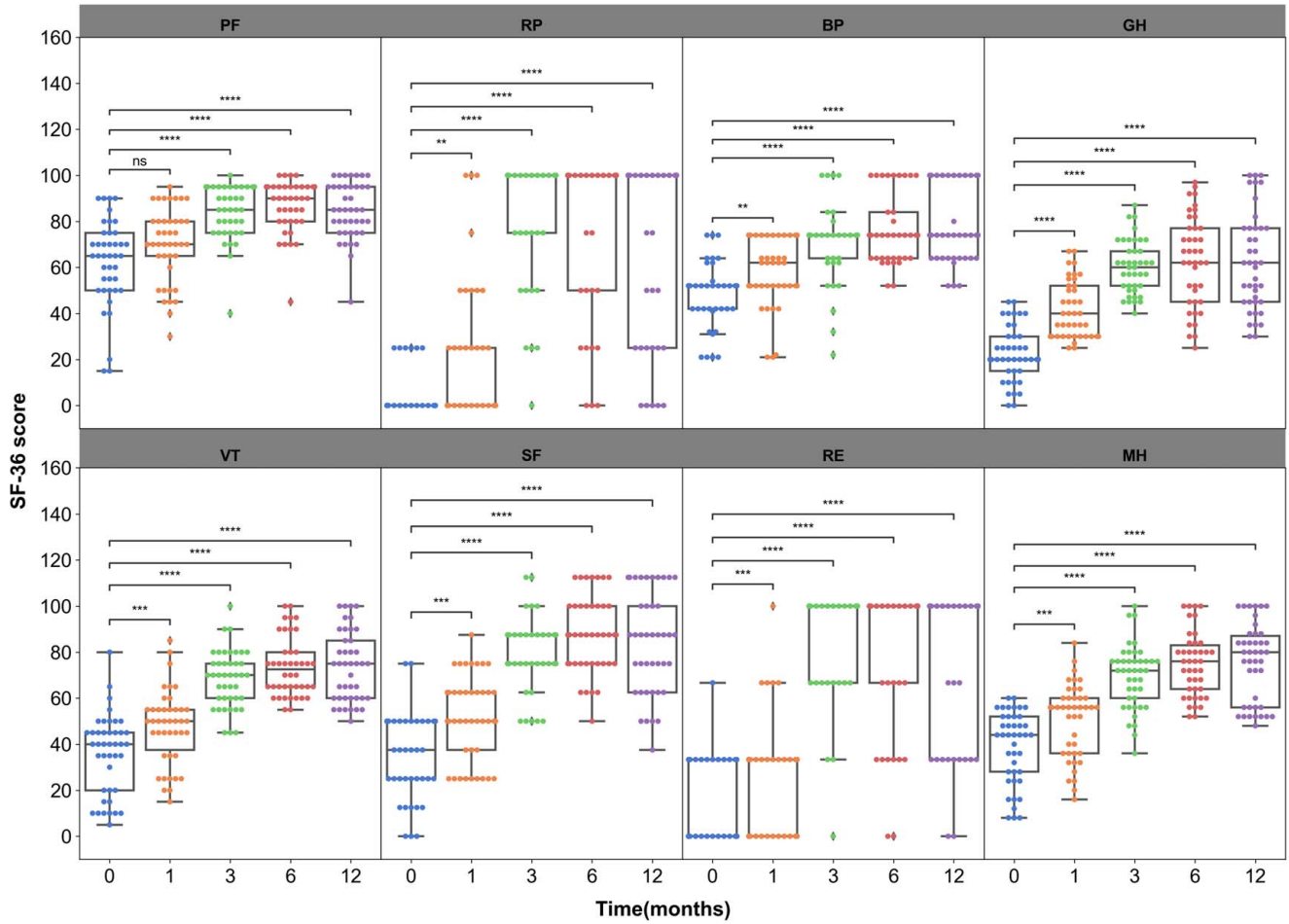

Figure 4. Eight domains of the 36-item Short Form Health Survey at baseline and at 1, 3, 6, and 12 months of follow-up. $^{**}P < 0.01$; $^{***}P < 0.001$; $^{****}P < 0.0001$. BP, bodily pain; GH, general health; MH, mental health; ns, no significance; PF, physical functioning; RE, role-emotional; RP, role-physical; SF, social functioning; VT, vitality.

Predictors of recurrent stricture

A total of 20 patients experienced recurrent stricture in the study. As shown in Table 2, various factors associated with recurrent stricture were evaluated, including age, sex, stricture etiology, Mellow–Pinkas score, stricture location, stricture length, stricture diameter, and the time of wearing SHIB (whether ≤4 months or not). The time of wearing SHIB depended on the condition of the ulcer condition. We found that stricture etiology ($P < 0.001$), length ($P = 0.003$), location ($P < 0.001$), and wearing time ($P < 0.001$) were all independent predictors of recurrent stricture. Multivariate Cox regression analysis revealed that stricture etiology [Hazard Ratio (HR) = 2.84, 95% CI (1.08–7.49); $P = 0.035$] and wearing time [HR = 8.76, 95% CI (2.88–26.64); $P < 0.001$] were significant independent predictors of stricture recurrence (Table 2). According to the survival analysis, stricture etiology and wearing time (≤4 months or not) were both associated with esophageal recurrent stricture ($P < 0.001$, $P < 0.001$) (Supplementary Fig. 1, Supplemental Digital Content 2, http://links.lww.com/JS9/B724, Supplementary Fig. 2, Supplemental Digital Content 2, http://links.lww.com/JS9/B724).

Improvement in recurrent stricture

In Table 3, we compared some relevant factors between preplacement and postremoval of SHIB among the 20 patients with recurrent stricture. Before placing SHIB, the median stricture length at baseline was 5.03 ± 3.01 cm. After the removal of SHIB, the stricture length decreased to a median of 2.95 ± 2.15 cm when the 'first-time' stricture developed. In addition, the median dilation interval was significantly prolonged (20 vs. 57.5 days, $P < 0.001$). No significant improvements were observed in the median stricture diameter or dysphagia scores according to the Mellow–Pinkas scores.

Discussion

Our study shows that the SHIB is an effective and safe method for treating refractory BESs of different origins. The clinical success rate was 51.2% with a median treatment time of 104.0 days. All enrolled patients showed significant improvement in dysphagia scores during SHIB placement. The SHIB exhibited several advantages over traditional alternatives[1,6,16], including a higher success rate, a shorter treatment period, a lower frequency of

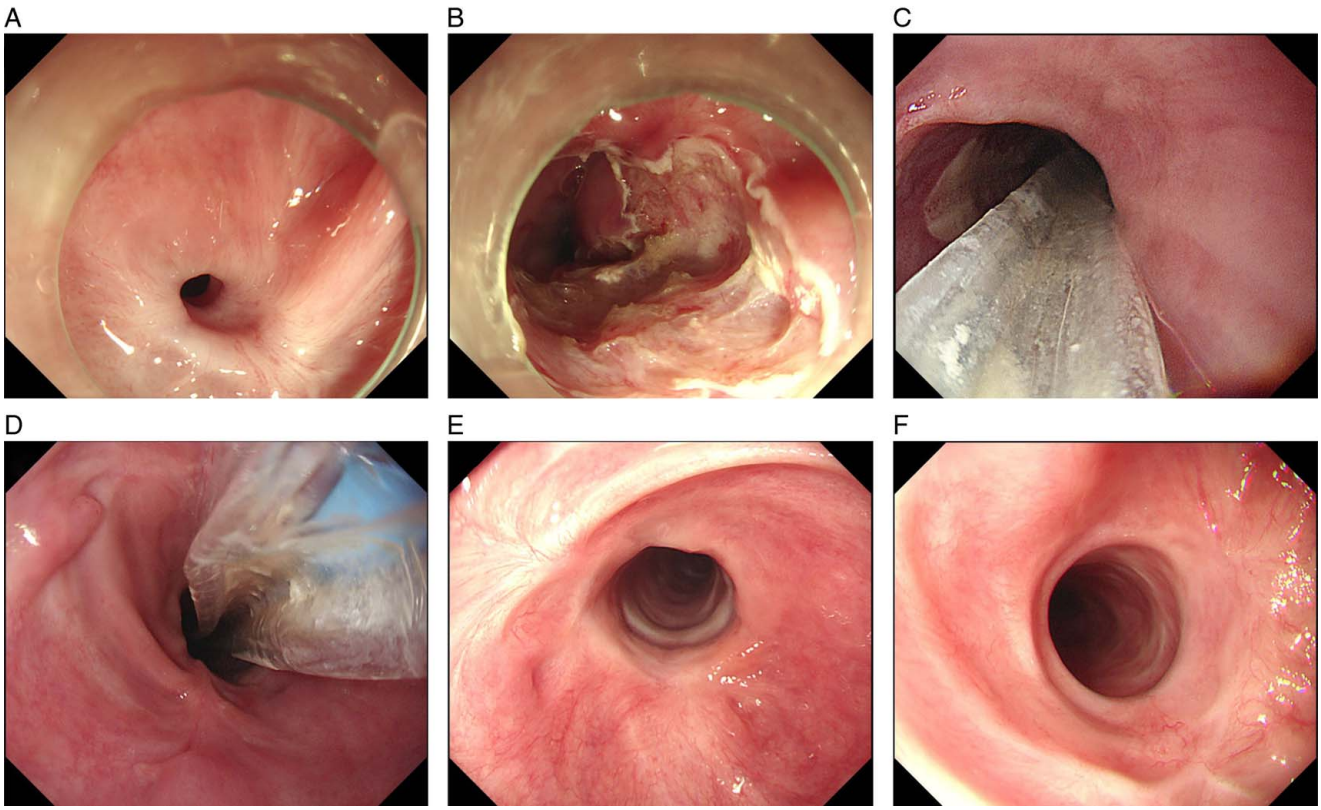

Figure 5. Representative case in the endoscopic group. A, The diameter of the stricture was 4 mm, and it was located at 24–27 cm from the incisors. B, Endoscopic incision therapy was performed in advance. C–D, The ulcerated area was gradually reduced which was observed at 3 and 12 weeks after the placement of SHIB, respectively. E, The balloon was removed after 16 weeks, at which time the ulcer had almost healed. F, No stricture occurred during the follow-ups at 12 months after removing SHIB.

hospital visits, a lower cost, and no serious complications, which collectively show that the SHIB is the most promising method at present for the treatment of refractory BESs.

The goal of SHIB is to free patients with refractory stricture as much as possible from repeated treatment and extra nutrition support. Traditional methods are costly and high-risk, and their overall effectiveness is suboptimal. In recent years, UK guidelines supported aggressive management of BESs in the early stages[1]. Nijmegen *et al*.[17] conducted a multicenter retrospective study, showing that dilation up to 16–18 mm in diameter was associated with fewer endoscopic dilation sessions. Furthermore, it also revealed that anastomotic and caustic strictures were associated with more endoscopic dilation sessions. Antoine reported a method of an early scheduled program of dilations, 10 patients enrolled eventually[18]. Although the success rate was 90%, the mean duration of treatment was 18.8 months, and almost 30% experienced serious complications. The long duration of treatment increases the economic burden and reduces the quality of life. The SHIB provides a buttress for only 4 months, resulting in a promising success rate. Thus, our findings support the UK guidelines.

To improve the efficiency and facilitate patients' operation at home, in 2018, Kahn introduced a new method of esophageal self-dilation therapy (ESDT), in which patients were required to learn to pass a flexible tapered dilator orally on their own to maintain esophageal luminal patency[19,20]. Although esophageal self-dilation therapy reduced the median number of endoscopic dilations, only 22.2% (8/36) of patients achieved free from 1-year repeated self-dilation. Three patients experienced significant adverse events, and one died related to self-dilation. In addition, the technique is not suitable for patients with angulated strictures or strictures that are associated with a distal esophageal diverticulum. A novel method of more effective, safer, and could be operated at home was urgently needed.

In the past, the placement of temporary metal stents for BESs was popular. However, a high migration rate, issues hyperplasia of stent ends and not suitable for strictures located in the cervical, which restricts its wider application[21–24]. Similar to a traditional metal stent, the SHIB provides a buttress during the process of artificial ulcer healing; however, it not only breaks the limits on the time and location of metal stent placement but also avoids the hyperplasia of granulation tissue. In the present study, patients could operate the SHIB easily at home by themselves, and adjust the balloon location if migration occurred, which not only dramatically reduced the frequency of hospital visits and financial burden of repeated dilations, but also improved the treatment effectiveness when compared to traditional EBD. Patients' eating was not affected by the placement of SHIB, and their quality of life was improved.

Esophageal strictures resulting from different etiologies inherently possess distinct characteristics. This variation is a key factor in the diversity of our study population's baseline characteristics, especially in age, sex, and tumor location. In addition, these characteristics were not found to be risk factor for

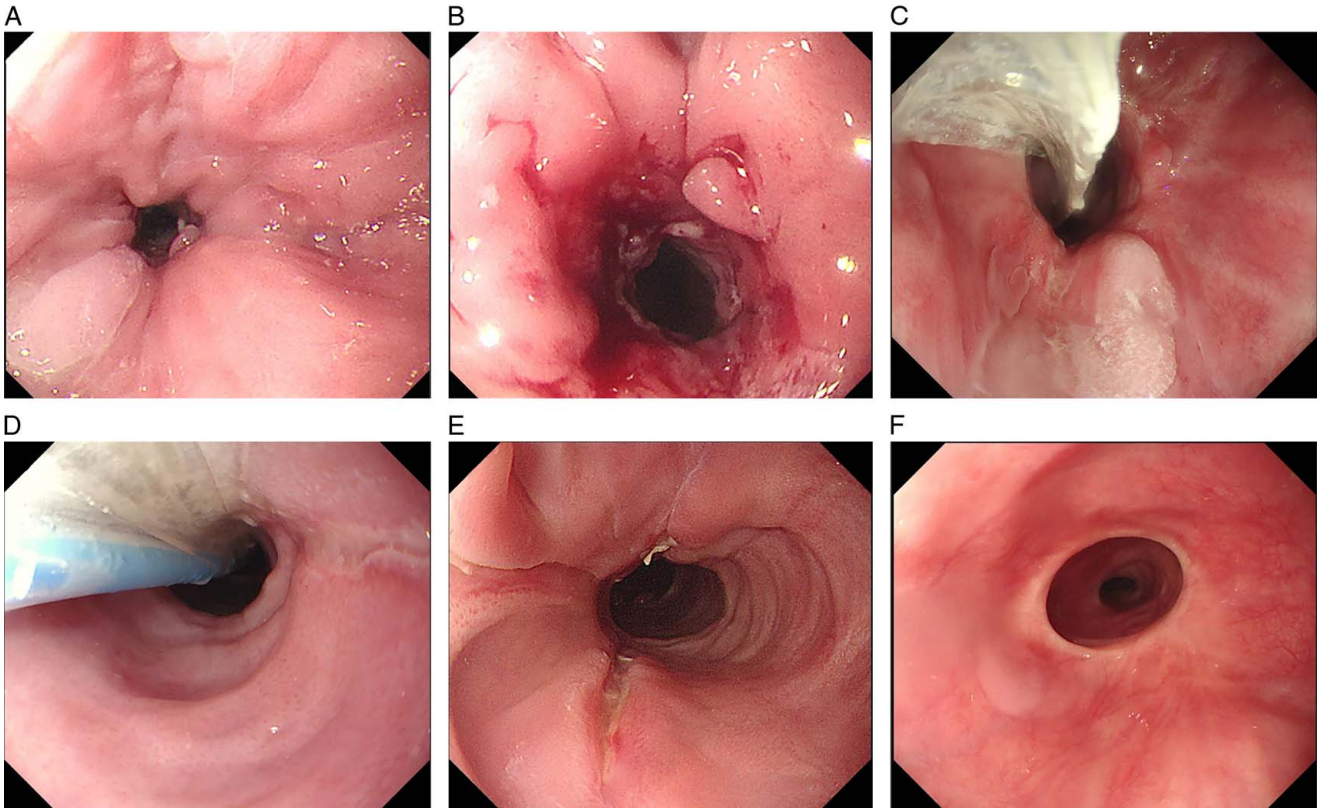

Figure 6. Representative case in the caustic group. A, The diameter of the stricture was 5 mm, and it was located at 29–31 cm from the incisors. B, Endoscopic balloon dilation was performed in advance. C–D, The ulcerated area was gradually reduced, which was observed at 3 and 7 weeks after the placement of SHIB, respectively. E, The balloon was removed after 12 weeks, at which time the ulcer had almost healed. F, No stricture occurred during the follow-ups at 17 months after removing SHIB.

predicting esophageal recurrent stricture with univariate analyses As a result, differences in baseline characteristics did not affect the study outcomes. Esophageal anastomotic strictures are often caused by postoperative complications, such as fistulas, leakage, infection, and anastomotic ischemia induce[25,26]. Caustic strictures are tender to be multiple in location[27]. So strictures in the above two groups were relatively longer and more complex than those in the endoscopic group, and the ulcer caused by the preliminary dilation strategy needed more time to recover, which led to a higher incidence of wearing time >4 months. On multivariate Cox regression analysis, stricture etiology and wearing time (>4 months or not) were both independent predictors of esophageal recurrent stricture. Additionally, patients experienced recurrent stricture exhibited a significant improvement in dysphagia during the period of wearing SHIB.

Table 2

Univariate and multivariate Cox regression analyses for predicting esophageal recurrent stricture.

	Univariate analysis			Multivariate analysis		
	HR	95% CI	*P*	HR	95% CI	*P*
Age, years	0.98	(0.95–1.00)	0.08			
Sex (vs. Female)						
Male	0.97	(0.32–2.89)	0.951			
Endoscopic group (vs. No)						
Yes	4.43	(1.79–10.94)	0.001	2.84	(1.08–7.49)	0.035
Mellow–Pinkas score (vs. 3)						
4	1.40	(0.58–3.36)	0.454			
Location (vs. nonmultifocal)						
Multifocal	8.41	(2.63–26.94)	<0.001	—	—	—
Median stricture length (vs. ≤2 cm)						
>2 cm	5.26	(1.74–15.90)	0.003	—	—	—
Median stricture diameter (vs. <5 mm)						
≥5 mm	0.65	(0.25–1.68)	0.369			
Wearing time (vs. ≤4 months)						
>4 months	10.12	(3.49–29.31)	<0.001	8.76	(2.88–26.64)	<0.001

–, negative value; HR, Hazard Ratio; SHIB, self-help inflatable balloon.

In the study, it was observed that the SHIB was well-tolerated by patients, and all patients expressed a strong preference for self-dilation over traditional endoscopic treatment, particularly after becoming accustomed to independent self-dilation. It is crucial to acknowledge that all patients received adequate psychological preparation and training before placing the new device. The greatest anxiety faced by patients was uncertainty of the SHIB's efficiency. The significant improvement of dysphagia after using SHIB, played a crucial role in overcoming this fear. All patients were satisfied with the effectiveness of SHIB. Furthermore, the treatment period in our study was only 4 months, far shorter than the 12–41.4 months reported in other studies[18,20,28].

As a result, not only was the medical burden of patients decreased, but also their quality of life was also improved. The mean BMI of all patients at 1, 3, 6, and 12 months were significantly improved compared with the baseline after placing

Table 3

Comparison between preplacement and postremoval of SHIB in 20 patients with recurrent stricture.

	Preplacement of SHIB	Postremoval of SHIB	*P*
Median stricture length, mean ± SD	5.03 ± 3.01	2.90 ± 2.15	0.001
Median stricture diameter, mean ± SD	3.75 ± 1.65	4.18 ± 1.66	0.368
Mellow–Pinkas score, *n*/*n* (3/4)	3.5 (10/10)	3.0 (13/7)	0.180
Interval dilation, days, median (range)	20.0 (14.0–26.8)	57.5 (29.5–73.3)	0.001

SHIB. Because patients needed time to grow accustomed to the SHIB, and their esophageal ulcers recovered gradually, the increasing trend of BMI was more significant at 3 month than that of 1 month. In addition, the HRQoL of all patients at 1, 3, 6, and 12 months showed significant improvement compared with baseline after placing SHIB, which revealed a better health condition of eight dimensions. The promising results suggest that the novel method could be an effective choice for patients with refractory BESs. More centers will participate in the clinical trial to further evaluate the effectiveness and safety of SHIB.

Perforation, delayed bleeding, and death were the most severe complications, which often reported in other studies. The rate was 12.9% in a largest retrospective study[10]. However, in the present study, none of the above complications were reported indicating the SHIB offers a safer treatment method compared with other current methods. Only mild adverse events were detected, such as discomfort in the throat, nose and esophagus, which often lasted only 1–2 weeks and were resolved without intervention. Future improvements in the construction material of the SHIB could decrease the rate of occurrence of adverse events.

The present study has some limitations. Firstly, although it is a prospective exploring study for SHIB in the treatment of esophageal strictures, the sample size was limited to 41 patients, making the analysis of confounding variables difficult. Secondly, this was a single-arm study without a comparison with other treatments. However, patients in our study were all diagnosed with refractory BESs and exhibited poor responses to other treatment methods. It served as a historical comparison to some extent. Finally, more attention should be given to the comfort of the patients, and further improvement of the construction material is needed.

In conclusion, our study showed that the use of a self-inflatable balloon has high efficacy and safety in treating refractory BESs of various origins, especially BESs caused by endoscopic resection. Stricture etiology and wearing time were independent predictors for recurrent stricture. A multicenter trial including more patients is needed to confirm the efficacy and safety of this method.

Ethical approval

The study was approved by the Institutional Review Board of the Chinses People's Liberation Army General Hospital (S2018-216-01).

Consent for publication

Consent for publication was obtained from all authors.

Consent to participate: Written informed consent was obtained from all the patients for their consent to participate in this study and for their data to be used for research purposes.

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Author contribution

E.L., N.C., L.L., L.L., W.G.: conception and design; N.C., E.L., L.L., L.L., W.G.: endoscopic procedure; L.L., N.X., Y.B., N.R., S.S., N.W., J.X.: data collection; L.L., P.W., N.R., J.X., K.H.: data analysis and interpretation; L.L., N.X., P.W.: drafting of the article; N.C. and E.L.: critical revision of the article. All authors contributed in the Final approval of the article.

Conflicts of interest disclosure

The authors who participate in this study have no conflicts of interest to declare.

Research registration unique identifying number (UIN)

1. Name of the registry: A novel self-inflatable balloon for treating refractory benign esophageal strictures: a prospective, single-arm, multicenter study.
2. Unique identifying number or registration ID: research registry9206.
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/browse-theregistry# home/registrationdetails/649c5c4f74da2b00272bf6d8/.

Guarantor

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Data availability statement

The data that support the findings of this study are available on reasonable request from the corresponding author. The data are not publicly available due to privacy and ethical restrictions.

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