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A comparison of three kinds of balloon dilatations for patients with benign esophageal strictures

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Benign esophageal strictures (BES) have been usually treated with balloon dilatation with occasionally drug-coated balloon (DCB) or large balloon dilatation. We compared the clinical outcomes of 3 types of dilatations: small balloon dilatation, DCB dilatation, and large balloon dilatation for the treatment of BES. This retrospective study evaluated 3 groups of 82 consecutive patients with BES who underwent dilatation of either small balloon (Group S, *n* = 25), DCB (Group D, *n* = 22) or large balloon (Group L, *n* = 35). Technical success, dysphagia score, safety and recurrence of stricture were collected and evaluated. Technical success rates of dilatation procedure were 88.7%, 87.1% and 89.7% in Group S, Group D and Group L, respectively (*P* = 0.9291). Rupture occurred in 8 dilatations: two (2.8%) in the Group S, one (3.2%) in the Group D and 5 (7.4%) in the Group L (*P* = 0.4109). The final scores in Group L (0.4 ± 0.9) was significantly lower than that in Group S (1.3 ± 1.5) or Group D (1.3 ± 1.4; *P* < 0.01). A total of 44/82 patients (53.7%) were cured with no dysphagia after the end of follow-up: 10 (40.0%) in the Group S, 9 (40.9%) in the Group D and 25 (71.4%) in the Group L. Group L showed the best clinical effectiveness among the three groups (*P* = 0.0272). Longer hospitalization was required in the Group D (median 21.0, interquartile range [IQR] 10.0–49.5) than in the Group S (median 14.0, IQR 9.0–24.0) or the Group L (median 12.0, IQR 8.0–24.0, *P* = 0.0112). More hospitalization cost was required in the Group D (median 6.9 months, IQR 3.7–11.2 months) than in the Group S (median 4.0 months, IQR 2.6–6.8 months) or the Group L (median 3.1, IQR 2.1–6.3, *P* = 0.0006). In conclusion, large balloon dilatation is a safe and effective treatment for BES, with higher clinical effectiveness, shorter hospitalization and lower hospitalization cost. The use of DCB seems least preferable, as they are associated with more hospitalization cost and few cases of clinical improvement.

Keywords Benign esophageal strictures, Drug-coated balloon, Small balloon dilatation, Large balloon dilatation, Stents

Abbreviations

BES	Benign esophageal strictures
DCB	Drug-coated balloons
CT	Computed tomography
IQR	Interquartile ranges

Benign esophageal strictures (BES) are often caused by esophagectomy, endoscopic submucosal dissection[1], ingestion of caustic substances, esophageal reflux, and radiation therapy[2–8]. Various treatments have been conducted in patients with BES, including push-type dilators[9], balloon dilatation[10–12], and stent placement[13,14]. As a standard therapy for BES, serial dilatation using bougies dilators or balloons[4,5,7], shows a high success rate of relieving stricture immediately after dilatation[5,7]. However, the recurrent stricture rate is still relatively high during long-term follow-up[15]. Repeated dilatations are associated with increased potential risk of developing complications, significant hospitalization costs and inconvenience. Additionally, temporary placement of esophageal stents shows discouraging outcomes due to the low clinical success rate and high rate of adverse event[3–8,16]. The treatment of BES lacks of effective treatment and remains considered challenging[3,6,8].

Currently, the choice of balloon varies between operators and lacks recommended criteria for optimal balloon diameter for BES[9,17]. Drug-coated balloons (DCB), as an effective treatment of artery stenosis[18,19], some

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researchers have also tried to use it in the treatment of BES, hoping to improve the treatment effect. Preliminary studies suggest that DCB seems to be safely and effectively for the treatment of BES[20] and benign intestinal strictures[21]. In this study, we compared the 3 types of dilatations: small balloon dilatation, DCB, and large balloon dilatation, for the treatment of BES.

Methods

Patients

This a retrospective, observational study. The study was approved by the Institutional Review Board of Zhengzhou university committee on human investigation and all methods were performed in accordance with the relevant guidelines and regulations. Written informed consent was obtained from all patients. Inclusion criteria: The patients had symptoms of dysphagia and were diagnosed with BES by computed tomography (CT) and endoscopy, including postoperative stenosis, stricture after endoscopic submucosal dissection, radiation induced stricture and so on. If CT and endoscopic diagnosis are suspicious for malignant stricture, further biopsy for pathological diagnosis was performed to exclude malignant stenosis. All records were de-identified and stored in encrypted computer once data were collected. Between December 2019 and August 2024, 82 consecutive patients with BES were enrolled. Patients underwent dilatation of either small balloon (Group S, $n=25$), DCB (Group D, $n=22$) or large balloon (Group L, $n=35$). The choice of balloon catheter is mainly based on the doctor's experience and preference, as well as the patient's willingness to treat and economic status, considering the potential increased risk of esophageal rupture of large balloon, and the possible increase of the economic burden of DCB catheter. Patients with malignant stricture or esophageal fistulas were excluded.

Definitions

The clinical success defined as successful relief of dysphagia symptoms (grade 0–1). Dysphagia was graded as previously reported standard[22,23]. Technical success was defined as successful dilatation confirmed by either endoscopy or fluoroscopy, with no major adverse events including procedure-related death, massive bleeding, aspiration or esophageal rupture. Esophageal rupture is classified and defined as 3 types according to previously reported criteria[24]. The stricture index was calculated by the formula: 100%-stricture diameter/normal diameter of esophagus × 100% [25].

Dilatation procedure

Chest CT and esophagogram or endoscopy was conducted, and all patients were as asked to fast for at least 8 h before the dilatation procedure (Fig. 1). Dilatation procedures were performed under either endoscopic or fluoroscopic guidance. The operators are endoscopists or interventional doctors with at least 10 years of work experience to avoid complications due to their operational inexperience. About 10 ml of iodine contrast was taken orally to show the stricture. A 5 F multipurpose catheter (Cook Corporation, Bloomington, USA) and guidewire were passed through the stricture. Small balloon (< 25 mm in diameter, Bard Peripheral Vascular, Inc; Cook Corporation, Bloomington, USA), large balloon (25–30 mm in diameter, Bard Peripheral Vascular, Inc; Cook Corporation, Bloomington, USA) or DCB (12 mm in diameter, 40, 60–120 mm in length, Beijing Xianreida Medical Technology Co., LTD) was delivered and dilated for 1–3 min (Fig. 2). An immediate esophogram was conducted to show the relief of stricture and the potential complication of rupture.

Follow-up

Assessments of dysphagia, esophagogram, chest CT or endoscopy were conducted during follow-up. Reintervention of dilatation is conducted for patients with recurrent stricture. Patients were followed up by telephone or outpatient visits until death or the follow-up end date of 30 September 2024. Survival data, dysphagia score, stenosis index and cause of death were recorded.

Statistical analysis

Data were shown as median with interquartile ranges (IQR) or means ± standard deviation (SD). Kaplan-Meier analysis was used for study the 5-year overall survival rates. Chi-square tests, one-way ANOVA or two-way ANOVA followed by Bonferroni post-hoc tests were performed using Prism 5.0 (GraphPad Software Inc, San Diego, Calif; https://www.graphpad.com/). Significance was considered when a $P<0.05$.

Results

Patients

Between December 2019 and August 2024, 82 patients (58 males and 24 females) with a mean age of 63.8 ± 12.7 years were enrolled in the study. Patients were diagnosed with BES by CT and endoscopy, and further biopsy for pathological diagnosis was performed to exclude malignant stenosis if CT and endoscopic diagnosis are suspicious for malignant stricture. In this study, benign postoperative esophageal stricture was the most common. The baseline characteristics and demographics were comparable among the 3 groups (Table 1).

Technical success and hospitalization

Total No. of dilatations of Group S, Group D and Group L were 71, 31 and 68, respectively, with technical success rates of 88.7%, 87.1% and 89.7%, respectively ($P=0.9291$). Longer hospitalization was required in the Group D (median 21.0, IQR 10.0–49.5) than in the Group S (median 14.0, IQR 9.0–24.0) or the Group L (median 12.0, IQR 8.0–24.0, $P=0.0112$). More hospitalization cost was required in the Group D (median 6.9 months, IQR 3.7–11.2 months) than in the Group S (median 4.0 months, IQR 2.6–6.8 months) or the Group L (median 3.1, IQR 2.1–6.3, $P=0.0006$).

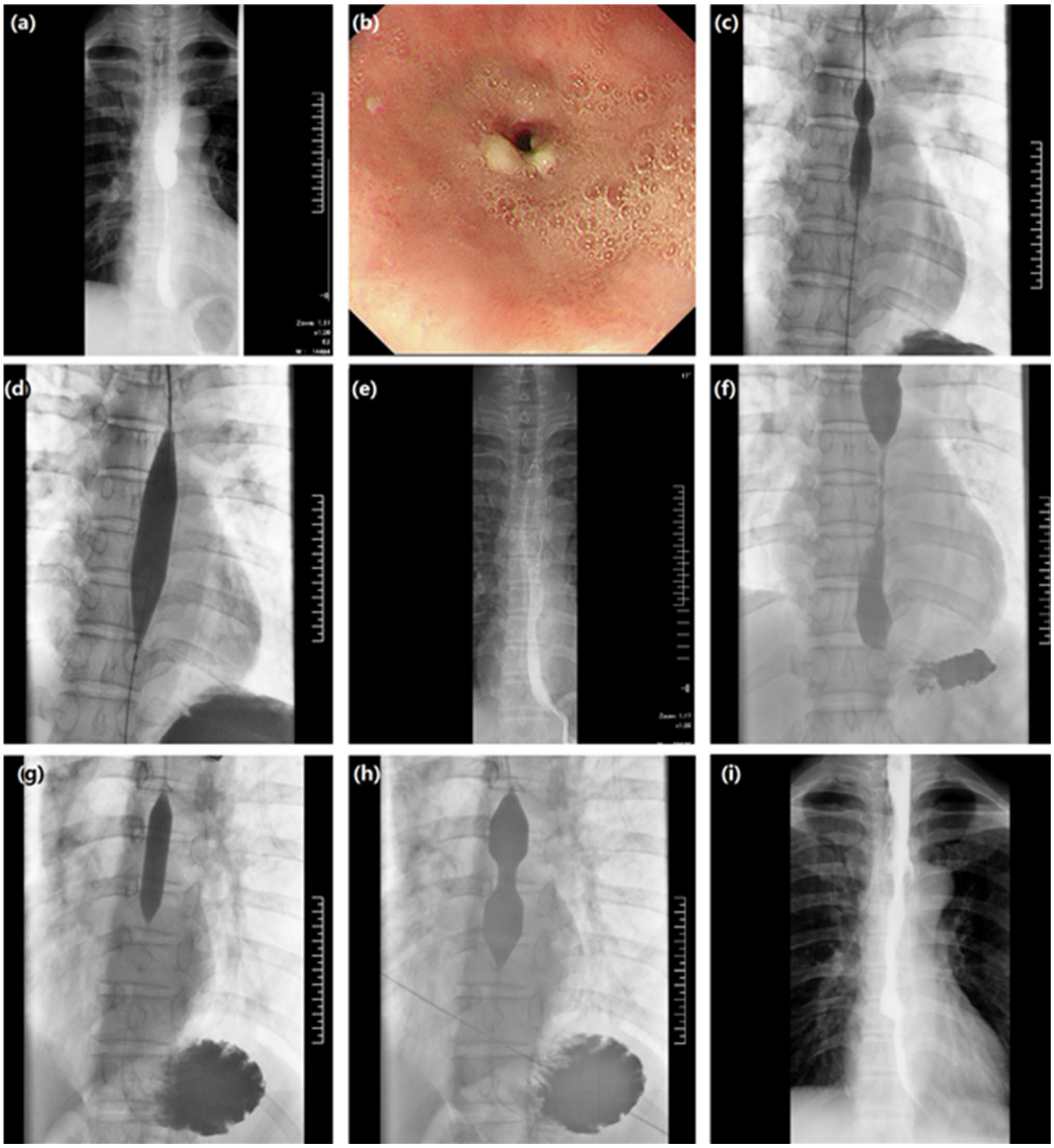

Fig. 1. A male patient with caustic esophageal stricture underwent DCB dilatation. (**a**) Esophagogram showed esophageal stricture at the level of the middle esophagus. (**b**) Endoscopic view of severe stricture through which the endoscope could not be passed. (**c**) A guidewire was passed through the stricture, and the first session of DCB (12 mm in diameter, 40 mm in length) dilatation was done after positioning the balloon within the stricture. (**d**) A postdilation was performed with an 18 mm small balloon (Bard Peripheral Vascular, Inc) for the patient due to residual stenosis after DCB dilatation. (**e**) Two day after dilatation, esophagography showed a relief of esophageal stricture, without esophageal rupture. (**f**) Recurrent stricture was observed 2.1 months after dilatation. (**g**) For the second session of DCB dilatation, a DCB catheter with 12 mm in diameter and 40 mm in length was used for dilatation. (**h**) Subsequently, a postdilation was immediately performed with a 20*55 mm small balloon (Cook Corporation, Bloomington, USA). (**i**) Repeated reintervention of DCB (12 mm in diameter, 40 mm in length) dilatation and insertion of 18*100 mm Bona stent is performed due to recurrent stricture 3.4 months after first dilatation.

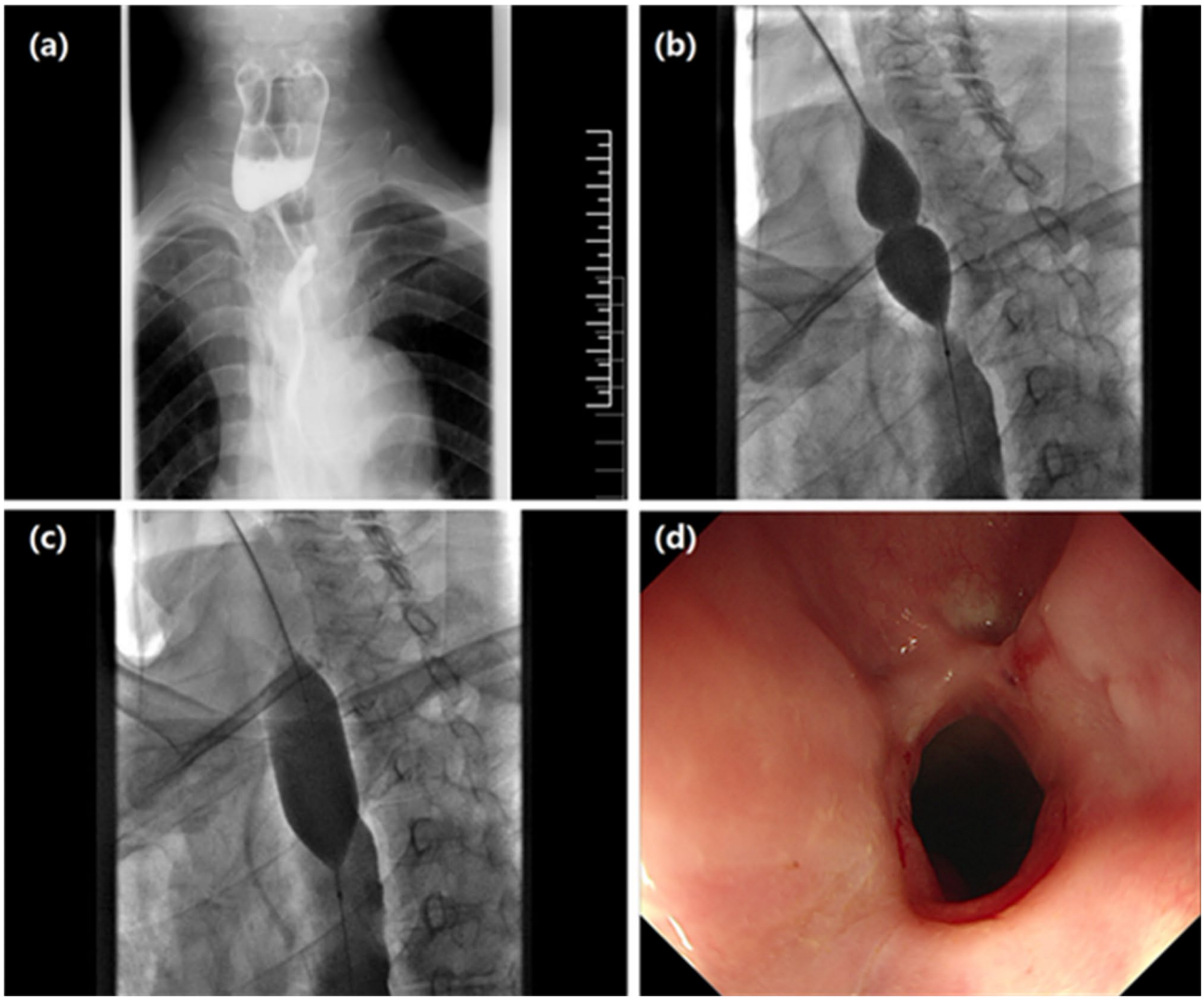

Fig. 2. A male patient underwent large balloon dilatation for anastomotic stricture. (**a**) An esophagogram showed severe stricture at the level of the sternoclevicular joint 2.8 months after esophagectomy for esophageal cancer. (**b**) Dilatation using Bard large balloon (26 mm in diameter, 40 mm in length) was done by positioning the balloon within the stricture. (**c**) The balloon catheter was dilated and inflated with 50% diluted contrast medium. (**d**) The esophagography showed a relief of esophageal stricture 10.1 months after dilatation, and the patient is able to eat normal diet during follow-up.

Clinical effectiveness and evaluation of stricture

Regarding clinical success, a total of 44 patients (53.7%) were cured with no dysphagia after the end of follow-up: 10 patients (40.0%) in the Group S, 9 patients (40.9%) in the Group D and 25 patients (71.4%) in the Group L. A total of 21 patients (25.6%) were clinically improved: 8 patients (32.0%) in the Group S, 5 patients (22.7%) in the Group D and 8 patients (22.9%) in the Group L. More than half of the patients showed recurrence of stricture after first dilation. Despite Group L showed the best clinical effectiveness ($P = 0.0272$), two patients (5.7%) developed ineffectiveness after repeated dilatation; one patient eventually received surgical resection and the other abandoned treatment.

Dysphagia score evolution for the 3 groups is shown in Table 2. Dysphagia scores improved significantly from the scores before dilatation to the scores after dilatation ($P < 0.05$) in the 3 groups. When comparing the dysphagia scores after dilatation, differences were not statistically significant among the three groups ($P = 0.2649$). The final scores in Group L (0.4 ± 0.9) was significantly lower than that in Group S (1.3 ± 1.5) or Group D (1.3 ± 1.4; $P < 0.01$). The final stricture diameter in Group S (9.4 ± 3.0 mm) and Group L (10.9 ± 4.4 mm) were higher than that in Group D (4.7 ± 4.8 mm; $P < 0.001$). Group L showed a lower final stricture rate when compared with the rate in Group D ($P < 0.001$).

Complications

As shown in Table 3, mild chest pain or bleeding was the most common complications among the 3 groups. Mild bleeding occurred in 62 (87.3%) dilatations in Groups S, in 26 (83.9%) dilatations in Group D and in 65 (95.6%)

	Group S	Group D	Group L	*P*-value
Total no. of patients	25	22	35	–
Gender, Male	20 (80.0)	14 (63.6)	24 (68.6)	0.4380
Mean age (years)	64.1 ± 12.2	59.4 ± 16.6	66.3 ± 9.6	0.1390
Course of disease (months)	3.0 (1.5, 10.5)	3.0 (2.0, 6.0)	3.0 (1.0, 6.0)	0.4001
Preoperative treatments				
Chemotherapy/radiotherapy or chemoradiotherapy	9 (36.0)	8 (36.4)	8 (22.9)	0.4320
Immune or targeted treatment	3 (12.0)	2 (9.1)	6 (17.1)	0.8160
Radical resection of esophageal cancer	17 (68.0)	10 (45.5)	25 (71.4)	0.1192
Other surgical treatments	6 (24.0)	7 (31.8)	9 (25.7)	0.8175
Cause of stricture				
Postoperative stenosis	17 (68.0)	10 (45.5)	25 (71.4)	
Endoscopic submucosal dissection	2 (8.0)	1 (4.5)	6 (17.1)	0.0659
Radiation induced stricture	2 (8.0)	4 (18.2)	1 (2.9)	
Others	4 (16.0)	7 (31.8)	3 (8.6)	
Severe/moderate/mild stricture	16 (64.0)/7 (28.0)/2 (8.0)	13 (59.1)/8 (36.4)/1 (4.5)	18 (51.4)/12 (34.3)/5 (14.3)	0.7121
Interval from surgery to dysphagia	3.3 (2.3, 5.8)	4.0 (2.3, 7.2)	3.0 (2.0, 5.0)	0.1185
Upper/middle/lower esophagus	19 (76.0)/4 (16.0)/2 (8.0)	14 (63.6)/5 (22.7)/3 (13.6)	32 (91.4)/1 (2.9)/2 (5.7)	0.1271
Comorbidities				
Old cerebral infarction	2 (8.0)	1 (4.5)	1 (2.9)	0.6576
Coronary disease	3 (12.0)	2 (9.1)	2 (5.7)	0.6874
Hypertension	5 (20.0)	1 (4.5)	7 (20.0)	0.2367
Diabetes mellitus	3 (12.0)	3 (13.6)	4 (11.4)	0. 9691

Table 1. Clinical characteristics of enrolled patients who underwent dilatation treatment. Data are presented as mean ± standard deviation or number (%). Others cause included post-caustic injury and peptic stricture and so on.

	Group S	Group D	Group L	*P*-value
Total no. of dilations	71	31	68	
Technical success	63 (88.7)	27 (87.1)	61 (89.7)	0.9291
No. of dilations	3.0 (1.0, 5.0)	2.5 (1.8, 6.0)	3.0 (2.0, 4.8)	0.9220
Total hospitalization (days)	14.0 (9.0, 24.0)	21.0 (10.0, 49.5)	12.0 (8.0, 24.0)	0.0112
Average hospitalization (days)	4.8 (3.6, 7.3)	7.9 (6.3, 10.0)	4.0 (2.9, 6.0)	0.0032
Total hospitalization cost, $\times 10^4$¥	4.0 (2.6, 6.8)	6.9 (3.7, 11.2)	3.1 (2.1, 6.3)	0.0006
Average hospitalization cost, $\times 10^4$¥	1.3 (0.9, 2.0)	2.8 (2.0, 3.6)	1.3 (1.0, 1.6)	< 0.0001
Total No. of hospitalizations	3.0 (2.0, 5.0)	3.5 (1.0, 7.0)	3.0 (2.0, 5.0)	0.35149
Duration of treatment, months	4.0 (1.1, 16.1)	5.3 (0.4, 22.0)	3.3 (1.7, 8.4)	0.1541
Dysphagia score, median (± SD)				
Before dilation	2.7 (0.7)	2.6 (0.69)	2.4 (0.6)	0.2016
Post-dilation	1.2 (1.0)	0.8 (1.3)	0.8 (0.9)	0.1897
Final score	1.3 (1.5)	1.3 (1.4)	0.4 (0.9)**	0.0085
Stricture diameter, median (± SD)				
Before dilation	2.4 (1.2)	2.2 (1.5)	2.7 (2.2)	0.6825
Post-dilation	8.6 (2.6)	9.5 (2.8)	10.1 (3.4)	0.2649
Final diameter	9.4 (3.0)***	4.7 (4.8)	10.9 (4.4)***	< 0.0001
Stricture rates, median (± SD)				
Before dilation	87.7 (7.5)	89.3 (7.2)	85.5 (11.9)	0.4267
Post-dilation	57.8 (15.0)	48.2 (14.7)	45.1 (19.8)	0.0538
Final rate	19.4 (27.1)	28.7 (27.2)	6.5 (14.8)***	0.0034

Table 2. Technical outcomes, hospitalization and stricture change. $^{**}P < 0.01$ vs. Group S or Group D. $^{***}P < 0.001$ vs. Group D.

	Group S	Group D	Group L	*P*-value
Complications, n (%)	71	31	68	
Mild bleeding	62 (87.3)	26 (83.9)	65 (95.6)	0.1213
Moderate bleeding	2 (2.8)	1 (3.2)	1 (1.5)	0.8188
Mild chest pain	67 (94.4)	29 (93.5)	66 (97.1)	0.6639
Severe chest pain	1 (1.4)	1 (3.2)	2 (2.9)	0.7863
Esophageal ruptures	2 (2.8)	1 (3.2)	5 (7.4)	0.4109
Recurrence after first dilation, n (%)	17 (68.0)	11 (50.0)	21 (60.0)	0.4543
Final clinical outcomes, n (%)				
Cured	10 (40.0)	9 (40.9)	25 (71.4)	
Improved	8 (32.0)	5 (22.7)	8 (22.9)	0.0272
Ineffective	6 (24.0)	8 (36.4)	2 (5.7)	
Loss of follow up, n (%)	1 (4.0)	0 (0.0)	0 (0.0)	1.0000
Deaths, n (%)	2 (8.0)	6 (27.3)	4 (11.4)	0.1479

Table 3. Complications, clinical outcomes and follow-up.

dilatations in Group L ($P=0.1213$). In the Group L, one patient (1.5%) experienced moderate bleeding, and two patients (2.9%) had severe chest pain during large balloon dilatation. In the Group S, two patients (2.8%) experienced moderate bleeding, and one patient (1.4%) experienced severe chest pain. Rupture occurred in 8 dilatations: two (2.8%) in the Group S, one (3.2%) in the Group D and 5 (7.4%) in the Group L ($P=0.4109$). There were no statistically significance in complications among the three groups, including esophageal rupture rates ($P=0.4109$).

Follow-up and recurrence

Only one patient was lost to follow-up in Group S. The median follow-up duration was 19.4 (IQR 10.0–49.5) months. After first dilatation, recurrences of stricture were observed in 17 patients (68.0%) Group S, in 11 patients (50.0%) in Group D and in 21 patients (60.0%) in Group L, and these differences were not significant ($P=0.4543$). During follow-up, one patient died of massive bleeding 13.1 months after first session of balloon dilation and one patient died of recurrent esophageal cancer 17.5 months later in Group S; four patients died of recurrent esophageal cancer and one patient died of massive hemoptysis and one patient of COVID-19 in Group D; one patient died of aspiration pneumonia and three patients died of tumor recurrence in Group L. The 5-year overall survival rates of Group S, Group D, and Group L were 90.8%, 64.3% and 67.3%, respectively.

Discussion

Various treatments have been conducted in patients with BES, including push-type dilators[9], balloon dilatation[10–12,17], and stent placement[11,13,14]. As a standard therapy for BES, serial dilatation using bougies dilators or balloons shows a high success rate of relieving stricture immediately after dilatation[5,7]. However, the recurrent stricture rate is still relatively high during long-term follow-up[15]. It's reported that dilatation using bougie dilators show a similar effectiveness but less hospitalization cost in comparison with balloon dilatation[25]. However, bougie dilators are theoretically more dangerous than balloon dilatation due to longitudinal shearing forces, and only 33.3% of patients are able to have normal after bougination alone[26]. Additionally, temporary placement of esophageal stents shows discouraging outcomes due to the low clinical success rate and high rate of adverse event[3–8,16]. Nowadays, the management of BES lacks of effective treatment and remains challenging[3,6,8].

Moreover, the choice of balloon varies between operators[9,10,17]. Although small balloon of less than 15 mm is recommended[9], larger dilatation with over 16 mm has been conducted to prolongate the dilatation-free period for benign anastomotic strictures[27]. The largest balloon with maximum diameter of 30 mm has also been used for the treatment of BES and Budd-Chiari syndrome in the expectation of better clinical efficacy[17,28]. Currently, the choice of balloon lacks recommended criteria for optimal balloon diameter for BES[9,10,17].

As an effective treatment of artery stenosis[18,19], DCB can reduce the occurrent vascular restenosis by means of homogenous delivery of antiproliferative drugs into the arterial wall. According to the above theory, some researchers have also tried to use it in the treatment of BES, hoping to improve the treatment effect. Preliminary studies suggest that DCB seems to be safely and effectively for the treatment of BES[20] and benign intestinal strictures[21]. Wang et al. conducted DCB dilatation for 9 patients with BES[20], and this kind of DCB is also used for benign intestinal strictures in 10 patients[21]. In this study, we compared the differences in the efficacy, safety and economic benefit of dilation treatment among 3 types of dilatations: small balloon dilatation, DCB, and large balloon dilatation, for the treatment of BES.

The 3 types of dilatations were similar in terms of technical success. Large balloon dilatation showed a higher clinical effectiveness at the end of the follow-up period, 71.4% patients were dysphagia free and 22.9% patients were dysphagia improved. Recurrent stenosis is the main cause of clinical failure, even in the large balloon group. Two patients (5.7%) developed ineffectiveness after repeated dilatation; one patient eventually received surgical resection and the other abandoned treatment. Additionally, recurrent malignant stricture frequently occurs after surgical resection. All patients were confirmed to have BES when they started receiving balloon dilation. With

the development of the disease, some patients have tumor recurrence, and even death. We did not exclude these patients; this heterogeneity might have affected the success rate of the balloons.

According to our findings in this study, the use of DCB seems least preferable, as they are associated with more hospitalization cost and few cases of clinical improvement. The first possible explanation is that the DCB used in this study was only 12 mm in diameter, and the small diameter is the most important factor may lead to the unsatisfactory clinical efficacy. The dilatation using large balloon showed a better efficacy, which indicated balloon diameter is most likely the most critical factor for the outcomes of BES and the importance of diameter selection of balloon. Secondly, the sessions of DCB dilatation are small due to the high cost, which also reduces the efficacy to some extent. In addition, it should be noted that the application of DCB as a new treatment for benign esophageal stenosis is overindicated and requires additional time for application approval and product acquisition. This increases the period of hospitalization, and the overall treatment costs to some extent increases. But in any case, the use of a DCB for BES should be cautious. Considering the high cost and uncertain efficacy, the DCB should not be recommended as the preferred treatment method for patients with BES.

Regarding the safety concerns, the major adverse events were esophageal rupture and massive bleeding. In this study, no massive bleeding or procedure-related death was observed. Mild chest pain and mild bleeding were commonly observed among three groups. Type I/II esophageal ruptures were observed in 2.8 to 7.4% of balloon dilatations, this is in accordance with previous studies[17,29]. It is reasonable to assume that larger balloons could be more effective, however some endoscopists fear complications. Theoretically, a larger balloon is associated with a higher risk of esophageal rupture. Our data showed that the risk of esophageal rupture was not significantly increased in large balloon group. Only type I or II rupture was observed rather than a type III rupture, which can be treated effectively by acid inhibitors, parenteral nutrition and anti-inflammatory drugs.

There are some limitations in this study. First, this is a single-center, retrospective study with no randomization, and there may be a selection bias in the study population. Second, we focused on the outcomes of different treatments without further dividing the subgroups of specific BES, the patients enrolled in this series are etiologically heterogeneous, and subgroup analysis of the specific stricture cannot be conducted due to small sample size. More prospective, multicenter studies on different types of BES are warranted in the future. Finally, a variety of treatments, including pre-dilation and post-dilation, may cause deviation in the efficacy evaluation among groups.

In conclusion, our data suggest that large balloon dilatation is a safe and effective treatment for BES, with higher clinical effectiveness, shorter hospitalization and lower hospitalization cost. The use of DCB seems least preferable, as they are associated with more hospitalization cost and few cases of clinical improvement.

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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X.W. Han and C.Q. Guo: guarantor of integrity of the entire study. P. Liu and Y.H. Bi: study concepts. X.W. Han and J.Z. Ren: study design.P. Liu, Y.H. Bi, and C.Q. Guo: literature research. P. Liu and Y.H. Bi: clinical studies. All authors: data acquisition. All authors: data analysis and statistical analysis.All authors: manuscript preparation.X.W. Han and J.Z. Ren: manuscript editing and review.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

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