Observational Study

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Long-term outcomes of large balloon dilatation for benign anastomotic stricture following surgical resection of esophageal cancer

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Abstract

Surgical resection of esophageal cancer may result in benign anastomotic strictures, which are usually treated by balloon dilatation. Here we reported the long-term outcomes of large balloon dilatation for benign anastomotic strictures secondary to esophagectomy for esophageal cancer. From February 2011 to December 2016, 27 esophageal cancer patients underwent large balloon dilatation for benign strictures following surgical resection. Clinical success rate, number of dilatation sessions, complication rate, and mortality rate were evaluated. A total of 27 patients developed a benign stricture at the esophagectomy site. A total of 50 dilatation sessions of large balloon were performed, with a mean of 1.8 sessions per patients (range 1.0–5.0). Only 1 perforation was observed (2.0% per dilatation session), and required no surgery. No procedure-related deaths were recorded. Large balloon dilation was technically successful in the remained 26 patients (96.3%). Dysphagia score and stricture index decreased significantly ($P < .0001$). Proximal diameter of stricture, stricture diameter and length decreased significantly. Patients were followed up for 36.3 ± 7.1 months, and 14 patients survived without dysphagia. The survival rates were 95.0%, 69.1%, 34.5% for 1, 5, and 9 years, respectively. The median survival was 96.0 months. Large balloon dilatation can be a safe and feasible treatment for benign anastomic strictures following surgical resection of esophageal cancer, with a low perforation rate. However, further study compared with small balloon dilatation is warranted.

Keywords: anastomotic stricture, balloon, dilatation, esophageal cancer, fluoroscopic

1. Introduction

Esophagectomy is still the standard treatment for esophageal cancer,[1] although interventional protocols were reported as palliation for malignant strictures.[2] Postoperative anastomotic stricture is one of the most common complications and may lead to malnutrition. The incidence of benign stricture after cervical anastomosis in a transhiatal esophagectomy can be up to 42%,[3,4] and about 39% of patients require serial dilatation, with a major complication rate of 0.4%.[3,5]

Although it is reported that esophageal plastic stents may provide an alternative approach to traditional dilatation for treating benign esophageal strictures.[6,7] Serial dilatation with balloon catheter[8–10] and push-type dilators[11] are usually performed with good clinical outcomes. However, Maloney bougies exert longitudinal shearing forces, which are theoretically dangerous than balloon catheter.

Moreover, the optimal diameter for dilatations of benign anastomic stricture is still unknown, although 13 to 15 mm in diameter is recommended[11] and larger dilatation with more than 15 mm in diameter is also performed.[8] In previous study, large balloon angioplasty is safe and effective for Budd-Chiari syndrome patients.[12] However, large balloon dilatation have not been reported for benign anastomic strictures. This study aimed to evaluate the safety and efficacy of large balloon dilatation for patients with anastomosis strictures following surgical resection of esophageal cancer.

2. Patients and methods

2.1. Patients

This study was approved by the Institutional Review Board of the First Affiliated Hospital of our University. Written informed consent was waived due to the retrospective study design.

2.2. Study design

From February 2011 to December 2016, all patients underwent large balloon dilatation for benign esophageal strictures were retrospectively analyzed. Included in the study were patients diagnosed with benign esophageal strictures without recurrence

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Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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(Figs. 1A and B and 2A–C); willing to receive large balloon dilation (25, 26, 30 mm); failed in repeated small balloon dilation (<25 mm) or push-type dilators. Excluded were patients with stricture within 3 months, malignant recurrent stricture, serious bleeding tendency, esophageal fistula, heart failure, severe infection, pregnant/breastfeeding women.

2.3. Balloon dilatation procedure

All procedures were performed by 2 radiologists with more than 10 years experience under fluoroscopic guidance and local anesthesia. Patients were placed on the fluoroscopic table in the supine position. About 5 mL of lidocaine was orally taken for local anesthesia of esophagus. A 5F multipurpose catheter (Cook Corporation, Bloomington, IN) and soft hydrophilic guidewire were used to cross the stricture through the mouth. Then the soft guidewire was withdrawn and a stiff guidewire was exchanged and introduced into the stomach. A large balloon catheter (25 or 30 mm, Cook Medical; 26 mm, Bard medical) was passed across the stricture. The balloon was filled with 50% diluted contrast medium once positioned. Dilatation was repeated for 2 to 3 times per session, and lasted about 1 to 2 minutes per dilation (Figs. 1C and D and 2D). The balloon catheter and guidewire was retracted following dilatation. About 3 to 5 mL of water soluble material was orally taken to look for esophageal perforation. The procedure generally lasted about 25 to 50 minutes. Patients were permitted to commence a soft diet about 24 hour later.

2.4. Outcome assessment and definition

Baseline demographics (gender, age, stricture diameter and length, comorbidities, number of dilation, and complication) were collected and recorded. The dimension of the stricture assessed by fluoroscopy before and after dilatation. Severe complications were esophageal perforation, death and massive hemorrhage.[13] The dysphagia score was compared before balloon dilation, immediately after dilatation, and during follow-up period. Ogilvie's dysphagia classification is used (grade 0: able to swallow with no dysphagia; grade 1: able to swallow solid food; grade 2: able to swallow soft solid food; grade 3: able to swallow liquids; grade 4: inability to swallow due to esophageal stricture or fistula).[2,14] The selected strictures were determined by the stricture index = 100%-stricture diameter/distal diameter of stricture × 100%.[15] Dilatation was considered clinically successful when the stricture index decreased to at least 20%, without severe complication.

2.5. Followed up

Esophagography and chest computerized tomography were performed during follow up (Figs. 1E and F and 2E and F). Survival

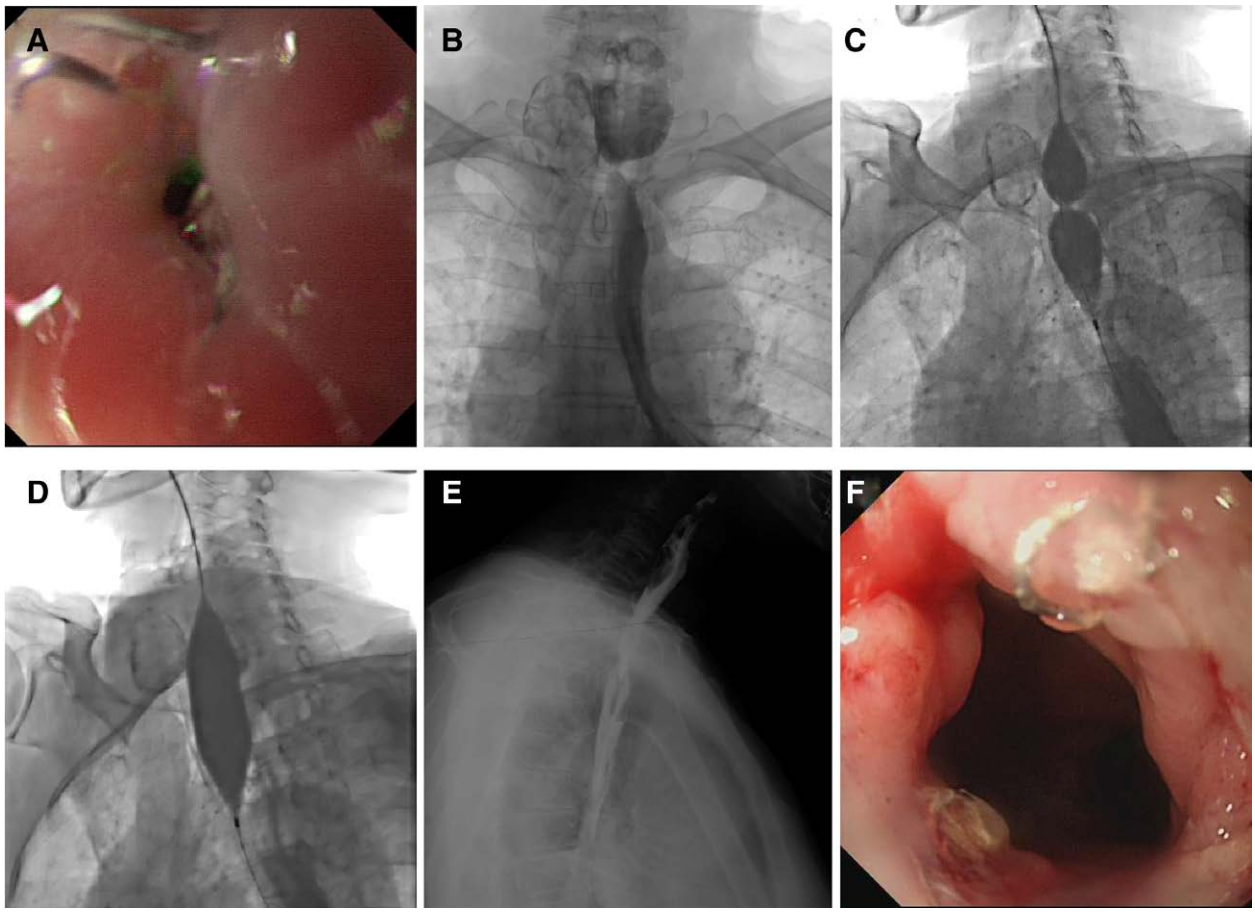

Figure 1. Seventy-one year-old female with esophageal anastomotic stricture secondary to esophageal resection. (A) Fibergastroscopy showed anastomotic stricture half a year after operation. (B) Anteroposterior views of esophagography show severe anastomotic stricture in the level of sternoclavicular joint. (C) Esophageal stricture "balloon waist" was shown on an inflated 26 mm diameter, 4 cm long balloon catheter. (D) The large balloon was fully dilated. (E) No stricture or leakage was observed after dilatation after water soluble contrast esophagogram. (F) Fibergastroscopy showed anastomotic stricture disappeared about 3 weeks after dilatation.

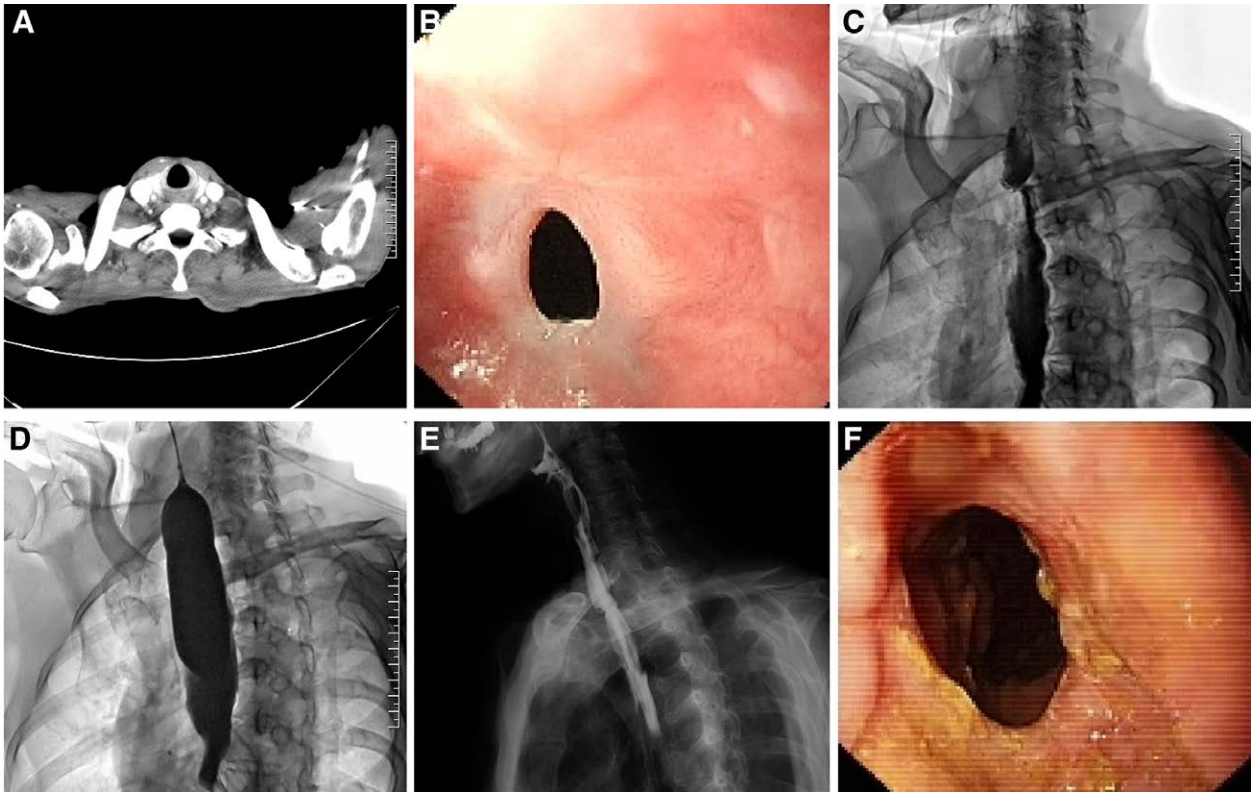

Figure 2. Seventy-two year-old male with esophageal anastomotic stricture secondary to esophageal resection. (A) CT showed anastomosis with no tumor recurrence. (B) Fibergastroscopy showed a 5 mm diameter anastomotic stricture 2.6 months after operation. (C) Esophagography show severe anastomotic stricture in the level of sternoclavicular joint. (D) The large balloon was fully dilated by a 30 mm diameter balloon catheter. (E) No stricture or leakage was observed after dilatation after water soluble contrast esophagogram. (F) Fibergastroscopy showed anastomotic stricture disappeared after dilatation. CT = computerized tomography.

time and death causes were recorded. Patients were followed up by outpatient visits or telephone call until death, loss of follow up or May 2021.

2.6. Statistical analysis

Data were shown as means ± standard error or median with interquartile ranges. Survival time was analyzed by Kaplan–Meier analysis. Data before and after dilatation were compared by the Student's *t* test using Prism 5.0 software (GraphPad Software Inc, San Diego, CA). Significance was considered when a $P < .05$.

3. Results

3.1. Patient characteristics

A total of 27 patients were enrolled in this study, 24 male and 3 female, with a mean age of 62.8 ± 1.8 years (range: 43–81 years). Twenty-four patients showed esophageal cancer, 3 patients showed esophageal-cardiac junction cancer after surgical resection. All patients showed benign anastomic stricture without recurrence confirmed by computerized tomography and/or fibergastroscopy. Twenty-five patients were esophageal squamous cell carcinoma by pathological examination. Twenty patients (74.1%) showed stricture in the upper esophagus after gastric pull-up and cervical anastomosis, 4 patients in middle esophagus after intrathoracic anastomosis and 3 patients in lower esophagus. Except for 2 patients were hand-sewn, stapler was sued in the remained 25 patients.

Five patients received postoperative chemotherapy, 1 patient underwent postoperative radiotherapy and 3 patients received radio-chemical therapy (Table 1). Five patients (18.5%) received small balloon dilation before large balloon dilatation; Two patients failed in bougienage dilatation due to severe stricture, and 1 patient underwent 3 dilatation sessions of bougienage but showed poor efficacy. A total of 50 dilatation sessions of large balloon were performed, with a mean of 1.8 sessions per patients (range 1.0–5.0).

3.2. Complications and safety

There was no procedure-related death during large balloon dilatation. A total of 5 complications (18.5%) were found, for a total complication rate of 18.5%. Four patients (14.8%) complained of mild to moderate chest pain after large balloon dilatation. One esophageal perforation was observed in the middle esophagus after large balloon dilatation, following clamp biopsy for distinguishing benign or malignant anastomic stricture. A covered esophageal metallic stent (20 × 120 mm) was implanted and 3 tubes were inserted. Fistula heals about 3 months later and the covered stent and 3 tubes were removed. The major complication rate of esophageal perforation was 3.7% per patient and 2.0% per dilatation session. Large balloon dilatation was technically successful in the rest of 26 patients (96.3%).

3.3. Follow-up

Dysphagia score and stricture index decreased significantly after large balloon dilatation ($P < .0001$). Although distal diameter stricture did not changed significantly, proximal diameter of stricture, stricture diameter and length decreased significantly after large balloon dilatation (Table 2). Four patients (14.8%) were lost in follow up, and remained 23 patients were

Table 1

Patient characteristics.

Characteristics	Values
Sex, male	24 (88.9%)
Mean age (range), yr	62.8 ± 1.8 (43–81)
Previous small balloon dilation	5 (18.5%)
Pre-dilation with small balloon	5 (18.5%)
Dilation sessions of large balloon (range)	1.8 ± 0.2 (1.0–5.0)
Diameter of large balloon, mm	28.8 ± 0.3
Median course of disease (range), mo	5.4 ± 0.8 (0.3–12)
Interval from surgery to stricture (range), mo	6.2 ± 0.8 (1.1–12.9)
Co-morbidities	
Hypertension	8 (29.6%)
Diabetes mellitus	3 (11.1%)
Coronary disease	3 (11.1%)
Location of stricture	
Upper esophagus	20 (74.1%)
Middle esophagus	4 (14.8%)
Lower esophagus	3 (11.1%)
Esophageal/Esophageal-cardiac junction cancer	24 (88.9%)/3 (11.1%)
Esophageal squamous cell carcinoma	25 (92.6%)
Postoperative chemotherapy or radiotherapy	9 (33.3%)

Table 2

Clinical outcomes before and after balloon dilation.

Variables	Before dilation	After dilation	*P* value
Stricture length, mm	21.3 ± 2.3 (6.0–50.0)	11.0 ± 2.4 (0.0–30.1)	.0069
Stricture diameter, mm	2.9 ± 0.5 (1.0–12.0)	12.2 ± 0.6 (9.2–16.9)	<.0001
Proximal diameter of stricture, mm	24.7 ± 1.9 (13.8–38.6)	19.0 ± 1.3 (11.7–29.1)	.0250
Distal diameter of stricture, mm	17.8 ± 1.2 (11.0–28.2)	18.9 ± 0.9 (12.5–26.0)	.4496
Stricture index	79.6 ± 2.3 (63.2–96.0)	33.5 ± 2.5 (12.4–44.7)	<.0001
Dysphagia score	2.7 ± 0.1 (2.0–4.0)	0.6 ± 0.2 (0.0–4.0)	<.0001

successfully followed up for a mean period of 36.3 ± 7.1 months. By the end of follow up, 14 patients survived without dysphagia, 3 patients survived with mild dysphagia (score 1); a total of 6 patients were dead, including 5 tumor progression, and 1 coronary heart disease. The survival rates were 95.0%, 69.1%, 34.5% for 1, 5 and 9 years, respectively. The median survival was 96.0 months.

4. Discussion

Benign anastomotic stricture is one of the most common complications of esophagectomy for esophageal cancer, which is mainly caused by excessive scar induced by reflux esophagitis or tissue repair response.[8,10] Other causes include caustic damage,[10] radiation esophagitis,[10] and sclerotherapy. The treatment strategies and prognosis of postoperative anastomosis are different between malignant and benign stricture.[16] Accurate diagnosis and early treatment can prolong life expectation and improve patient's quality of life.[16,17]

Benign anastomotic stricture usually occur 3 months after resection, the treatment is very difficult and prone to recurrence of stricture.[18] Management of benign anastomotic strictures often require serial balloon dilatation, with significant cost, potential risk, and inconvenience. Interventional protocols have been used for management of anastomotic complications, including anastomotic stricture[9] and anastomotic leakage.[19] Balloon dilatation show a better clinical results for anastomotic esophageal stricture than esophageal stricture induced by caustic ingestion or gastroesophageal reflux.[15,20] Balloon dilatation show a lower success rate for corrosive and peptic esophageal strictures,[20] dense scarring caused by diffuse esophageal involvement and long duration of symptoms may be the reason.

Said et al[15] reported that a total of 115 balloon dilatation sessions were performed in 25 patients, with a range of 1 to 14 procedures per patient (median 4 dilatations). In this study, a total of 50 dilatation sessions of large balloon were performed, with a mean of 1.8 sessions per patients (range 1.0–5.0). Our data indicated that patients with large balloon dilatation showed fewer dilatation sessions and less probability of stenosis recurrence. Besides, balloon dilatation is theoretically safer than bougienage, which do not exert longitudinal shearing forces and can be directly visualized under endoscopy guidance. Esophageal perforation was usually observed in Maloney bougies during blind passage into severe strictures,[21] with a reported high sessions of dilatation.[22]

Esophageal perforation is one of the most serious complications during balloon dilatation. A anastomosis of less than 3 weeks delay after resection may be in the early healing process and may put the stricture at risk of esophageal perforation.[23] A high perforation rate up to 33% was reported after balloon dilatation for esophageal stricture induced by caustic ingestion or gastroesophageal reflux.[20] Esophageal perforation caused by balloon dilatation can be observed in up to 2.7% of patients with postoperative anastomotic stricture.[15] Interestingly, the risk of esophageal perforation using large balloon dilatation in this study was similar and did not increase significantly. The safety of large balloon technique is acceptable and satisfactory comparing to previous report.[15] Only 1 esophageal perforation was observed in the middle esophagus after large balloon dilatation, following clamp biopsy for distinguishing benign or malignant anastomic stricture. Clamp biopsy is also the risk factor for esophageal perforation. Besides, this kind of benign esophageal perforation and malignant esophageal fistula can be successfully managed by interventional strategies, such as 3-tube method with or without covered stent placement.

In order to reduce the risk of esophageal perforation, following technical precautions should be noted during balloon dilatation: a balloon longer than the stricture should be used to avoid balloon migration during dilatation; a large balloon diameter is safe, but should be gradually and slowly dilated, avoid rapid dilatation during a single episode; balloon should be theoretically placed in the middle of the stricture, but it is more appropriate to place it 5 to 10 mm below the middle. Balloon should be pulled moderately during the process of dilatation, so that the balloon can be fixed stably and avoid shear force caused by migration; patients undergoing dilation under local anesthesia may be irritable and involuntary swallowing due to pain and other discomfort, and may easily cause balloon migration. Therefore, general anesthesia should be safer. Water soluble contrast should be used immediately after dilatation to detect perforation and to prevent mediastinitis and frank sepsis. Esophageal perforation should be treated as soon as possible, otherwise overall mortality is high if delay after 24 hours.[23]

There are limitations in this study. The main weakness of this study is the lack of control group. However, this study focuses on discussing the feasibility and safety of large balloon dilation and comparative studies with small balloon dilatation is wanted in the future. Besides, this is retrospective study performed in a single-center and the sample is relatively small.

In conclusion, large balloon dilatation can be a safe and feasible treatment for benign anastomic strictures following surgical resection of esophageal cancer, with a low perforation rate. Although small balloon technique is widely applied nowadays, large balloon dilatation may be a new option for benign anastomic strictures in the future. However, further study compared with small balloon dilatation is warranted.

Author contributions

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Formal analysis: Yonghua Bi.
Investigation: Yonghua Bi.
Methodology: Xinwei Han.
Project administration: Jianzhuang Ren.
Supervision: Jianzhuang Ren, Xinwei Han.
Writing – original draft: Yonghua Bi.
Writing – review & editing: Jianzhuang Ren, Xinwei Han.

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