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Original Article

Safety and Efficacy of Serial Endoscopic Dilatation for Benign Esophageal Strictures

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A B S T R A C T

Background: Benign esophageal strictures cause significant morbidity due to progressive dysphagia and impaired quality of life. Serial endoscopic dilatation is the standard treatment; however, recurrence and procedure-related complications remain concerns. This study evaluated the safety and efficacy of serial endoscopic dilatation in patients with benign esophageal strictures.

Methodology: A prospective observational study was conducted at Ayub Teaching hospital involving 80 adult patients with confirmed benign esophageal strictures. Patients underwent serial endoscopic dilatation using balloon or bougie techniques. Demographic characteristics, stricture etiology, number of sessions, dysphagia improvement, treatment success, and complications were assessed.

Results: The mean age was 44.8 ± 15.6 years, with males comprising 53.8% of participants. Corrosive injury (36.3%) was the most common etiology, followed by peptic strictures (31.3%). Technical success was achieved in 97.5% of patients, while clinical success was observed in 92.5%. The mean number of dilatation sessions was 3.1 ± 1.2. Dysphagia scores significantly improved after treatment (3.3 ± 0.6 vs. 1.1 ± 0.7; p<0.001). Complications were uncommon, including chest pain (12.5%), mucosal tears (6.3%), minor bleeding (2.5%), and perforation (1.3%).

Conclusion: Serial endoscopic dilatation is a safe and effective treatment for benign esophageal strictures, providing significant symptomatic improvement with a low complication rate.

Keywords: Dysphagia; Esophageal Stenosis; Esophagoscopy; Gastrointestinal Endoscopy; Treatment Outcome.

Introduction

BES are a major cause of dysphagia and a major impairment of quality of life in the world. These are caused by narrowing of the esophageal lumen due to fibrotic changes caused by various inflammatory, traumatic, infection or iatrogenic insults. Despite the decreased incidence in developed countries due to improved treatment of gastroesophageal reflux disease (GERD) and the relative rarity with which proton pump inhibitors (PPIs) are used, benign strictures do have a significant clinical impact, especially in low and middle-income countries, where corrosive ingestion, undiagnosed GERD, postsurgical complications, and infectious causes are common.[1,2] This progressive narrowing of the lumen can result in a failure to swallow solid foods and eventually fluids, which can cause malnutrition and weight loss, aspiration pneumonia and significant social distress. Therefore, early diagnosis and good management of this condition is key to ensure that swallowing function is recovered and long-term complications are avoided.

Benign esophageal strictures are a diverse group of conditions of many different causes and different pathological features. In western countries, peptic strictures due to chronic reflux of acid make up a significant portion of cases, while corrosive ingestion is one of the most common causes in many countries in Asia and elsewhere.[3] Other reported causes are postoperative strictures (after esophagectomy or bariatric surgery), radiation-induced fibrosis, eosinophilic esophagitis, Schatzki rings, congenital strictures and strictures following EMR and ESD.[4] Whatever the cause may be, over time, this inflammation will cause collagen to be deposited and fibrosis to occur in the esophageal wall, which will lead to the formation of scars around the circumference of the esophagus and lead to progressively narrowing lumens.

Patients who have benign esophageal strictures usually complain of a progressive dysphagia that starts with solid foods and then progresses to semisolids and liquids. Other symptoms include difficulty swallowing (dysphagia), regurgitation, chest pain, recurrent aspiration, and unintended weight loss. In clinical evaluation, careful history taking, upper gastrointestinal endoscopy, contrast esophagography and cross-sectional imaging (when indicated) are used to rule out malignancy, and to determine location, length and complexity of the stricture.[5] Endoscopic assessment is still the gold standard, as it allows direct visualization, biopsy if

necessary, and can be used for therapy at the same time. Clinically, it is important to be able to differentiate between simple and complex strictures as this translates to lower treatment success, higher rates of recurrence, and procedural difficulty with the treatment of a complex lesion.

Being minimally invasive, technically successful, and safe, endoscopic dilatation is now the treatment of choice for benign esophageal strictures. The main purpose of dilatation is to break up the fibrotic tissue, widen the esophageal lumen, relieve the dysphagia, and enhance nutritional status with minimal complications. There are two principal techniques; bougie dilatation with Savary-Gilliard or Maloney dilators or balloon dilatation with through-the-scope (TTS) balloons. So far there is no evidence that either modality is better, and the decision will be based on the stricture characteristics, the experience of the operator and the preference of the institution.[6] Unlike bougie dilators, balloon dilators apply force radially, but not longitudinally while passing through the stricture.

The majority of strictures are benign and do not need to undergo a single therapeutic session but rather serial endoscopic dilatation. Repeated procedures facilitate progressive dilation of the narrowed lumen and minimize the potential for esophageal perforation that is caused by over-dilation. The clinical guidelines state that progressive dilation should be performed with the "rule of three" in each session, defined as making no more than three successive diameter increments, when resistance is encountered, although recent reports indicate that customized procedures may be equally safe in certain patients.[7] The goal of serial dilatation is to keep the diameter of your esophagus about 15 to 18 mm, large enough to allow you to swallow normally in most people. The amount of sessions, however, will differ significantly depending on the etiology, length, severity and associated fibrosis of the strictures.

Although effective, recurrence is a major problem in the treatment of benign esophageal strictures. About 30-40% of patients will develop recurrent dysphagia, necessitating repeat interventions, especially in patients with corrosive injuries, radiation-induced fibrosis, long-segment or anastomotic narrowing. Recurrent and refractory strictures – failure to achieve an adequate lumen after multiple dilatation sessions – are particularly difficult clinical situations. To reduce recurrence, adjunctive treatments including intralesional corticosteroid injection, topical mitomycin-C application, temporary self-expandable stents, endoscopic incisional therapy, and self-dilatation have been investigated, but evidence to support the routine use of these treatments is still mixed.[9]

Safety is a major concern when dilating serially, as there are potential complications, such as tearing of the mucosa, bleeding, chest pain, bacteremia and, most importantly, esophageal perforation. Luckily, perforation is rare, and occurs at rates of less than 1% for experienced endoscopists when these procedures are carried out according to a standardized technique.[10] With careful patient selection, the use of fluoroscopy during selected complex strictures, progressive dilatation and following evidence based procedures, serious complications are significantly reduced. In addition, over the last 20 years, the use of new endoscopic accessories, better imaging and better procedural skills have also helped ensure safer outcomes.

International gastroenterology societies have made detailed recommendations, all of which stress the need for individualized management strategies dependent on the characteristics of the stricture. The American Society for Gastrointestinal Endoscopy (ASGE) and British Society of Gastroenterology (BSG) recommend endoscopic dilatation as first-line treatment in symptomatic benign strictures with appropriate treatment of the underlying etiology long-term acid suppression for peptic disease and dietary and pharmacological therapy for eosinophilic esophagitis.[11,12] It is not only mechanical dilatation that is important for successful long-term results but also control of the underlying pathological process to avoid recurrent fibrosis.

Excellent technical success rates over 90% have been shown in several observational studies and systematic reviews as well as significant improvements of the dysphagia score and patient reported quality of life with serial endoscopic dilatation.[13,14] However, there is significant variability in the suggested time between sessions, preferred dilatation method, risk factors for recurrence and long-term clinical outcome for various aetiologies. They emphasize the importance of institution-specific data to assess procedural success, complication rates, and risk factors for treatment failures, especially in countries where corrosive strictures are still relatively prevalent.

The growing use of therapeutic endoscopy and the continued prevalence of benign esophageal strictures raise the question of whether or not serial ED is safe and effective.[15] This evidence can guide local practice, optimize treatment protocols, highlight patient groups at increased risk of recurrence and enhance long-term swallowing outcomes, while reducing procedure-related complications. The present study is aimed to assess the safety, clinical efficacy, technical success, and outcomes of the treatment of benign esophageal strictures using serial endoscopic dilatation in patients in a tertiary care hospital.

Methodology

This Cross Sectional study was performed in the Department of Cardiothoracic Surgery, Ayub Teaching Hospital Abbottabad for 6 months from Oct 2022 to April 2023 after approval from the Institutional Ethical Review Committee. All participants signed informed consent before participating in the study, and the study was conducted in compliance with the Declaration of Helsinki (2013 revision) and Good Clinical Practice (GCP) guidelines. Eighty consecutive patients with symptomatic benign esophageal strictures (ES) diagnosed by upper gastrointestinal endoscopy and/or contrast esophagography and on a program of serial endoscopic dilatation (DED) were included in the study. Patients with malignant esophageal strictures, active esophageal perforation, esophageal varices, severe coagulopathy (INR>1.5 or platelet count <50,000/mm³), uncontrolled cardiopulmonary diseases that precluded endoscopy, pregnancy, previous esophageal stent placement, and those who refused to give informed consent were excluded.

A standardized proforma was used to document baseline demographic and clinical information, such as age, sex, symptoms, duration of dysphagia, etiology of stricture, location, length, and degree of luminal narrowing. The severity level of dysphagia was evaluated by Mellow-Pinkas Dysphagia Score before the first dilatation session and at the follow-up visits. Standard upper gastrointestinal endoscopy was used to obtain all the procedures under conscious sedation and performed by experienced consultant gastroenterologists. Through-the-scope controlled radial expansion (CRE) balloon dilators or Savary-Gilliard bougie dilators were used to perform serial dilatation based on the characteristics of the stricture and operator preference. Each session was done with gradual dilatation, while following the known safety principles; the desired luminal diameter was 15-18 mm, wherever clinically feasible. Patients who needed more than one session of treatment had serial dilations every 2-3 weeks until a satisfactory symptomatic result and adequate patency of the lumens was obtained.

The primary outcome measures were technical success (passage of the dilator across the stricture with the desired luminal diameter) and clinical success (improvement of at least one grade in dysphagia on the Mellow-Pinkas Dysphagia Score and the ability to tolerate oral intake). Secondary outcome measures included number of dilation sessions needed, recurrence of dysphagia that required repeat intervention during the study period, and procedure-related complications (chest pain, mucosal tears, bleeding, perforation, hospitalization, and mortality). Immediate post-procedural complications were determined for all patients and clinical follow-up was carried out until the end of the treatment protocol.

The collected data were analysed and entered into the Statistical Package for the Social Sciences (SPSS) software version 26.0 (IBM Corp., Armonk, NY, USA). Data were reported as mean ± standard deviation (SD) or median (IQR) depending on the distribution of data and categorical variables were reported as frequencies and percentages. For pre- and post-dilatation dysphagia scores, the paired t-test or Wilcoxon signed-rank test was used, while the Chi-square test or Fisher's exact test was used for associations between categorical variables. A p-value of < 0.05 was taken as statistical significance.

Results

During the study period, a total of 80 patients with benign esophageal strictures received serial endoscopic dilatation. The average age of the participants was 44.8 ± 15.6 years (range 18-76 years) and 42.5% of them were in the 31- to 50-year-old age group. Of the total population studied, 53.8% (n=43) were male and 46.2% (n=37) were female. All patients presented with progressive dysphagia (100%), followed by weight loss (46.3%), regurgitation (31.3.) and odynophagia (18.8.). The most common etiology was corrosive esophageal injury (36.3%), followed by peptic strictures (31.3%), postoperative anastomotic strictures (18.8%), radiation-induced strictures (8.8%) and eosinophilic esophagitis (5.0%).

Table 1. Baseline Demographic and Clinical Characteristics of the Study Population (n=80)

Variable	(n)	(%)
Age Group (years)		
18–30	18	22.5
31–50	34	42.5
51–70	22	27.5
>70	6	7.5
Gender		
Male	43	53.8
Female	37	46.2
Etiology of Stricture		
Corrosive injury	29	36.3
Peptic stricture	25	31.3
Anastomotic	15	18.8
Radiation-induced	7	8.8
Eosinophilic esophagitis	4	5.0
Presenting Symptoms*		
Dysphagia	80	100
Weight loss	37	46.3
Regurgitation	25	31.3
Odynophagia	15	18.8

Technical success of serial ESD was 78 (97.5%) and clinical success (defined as reduction of dysphagia score of at least one grade with improvement in swallowing) was seen in 74 (92.5%) patients. The average number of dilatation sessions needed was 3.1 ± 1.2, and 45.0% of the patients needed 3 sessions. There was a significant improvement in the mean Mellow-Pinkas Dyhagia score from 3.3 ± 0.6 at the start of treatment to 1.1 ± 0.7 at the end of serial dilatation (p<0.001).

Table II: Treatment Outcomes Following Serial Endoscopic Dilatation	
Variable	Value
Mean number of dilatation sessions	3.1 ± 1.2
Technical success	78 (97.5%)
Clinical success	74 (92.5%)
Mean pre-treatment dysphagia score	3.3 ± 0.6
Mean post-treatment dysphagia score	1.1 ± 0.7
Mean improvement in dysphagia score	2.2 ± 0.8
Patients requiring repeat intervention during follow-up	12 (15.0%)
P-value (pre- vs post-treatment dysphagia score)	<0.001

The risk of procedure related complications was low and mostly minor. Ten patients (12.5%) suffered from mild, transient chest pain, and five (6.3%) had minor mucosal tears. There were 2 cases of self-limited bleeding (2.5%) that were treated conservatively without blood transfusion and surgery. One patient (1.3%) had esophageal perforation that was surgically treated. In the study period, no deaths occurred as a result of the procedure.

Table II: Procedure-Related Complications.		
Complication	Frequency (n)	Percentage (%)
No complication	62	77.5
Chest pain	10	12.5
Mucosal tear	5	6.3
Minor bleeding	2	2.5
Esophageal perforation	1	1.3
Procedure-related mortality	0	0

The risk of procedure related complications was low and mostly minor. Ten patients (12.5%) suffered from mild, transient chest pain, and five (6.3%) had minor mucosal tears. There were 2 cases of self-limited bleeding (2.5%) that were treated conservatively without blood transfusion and surgery. One patient (1.3%) had esophageal perforation that was surgically treated. In the study period, no deaths occurred as a result of the procedure.

Figure 2. The incidence of complications associated with procedure in a series of ED. Although minor complications with transient chest pain were more common, only one patient experienced esophageal perforation, reflecting the good safety profile of serial endoscopic dilatation.

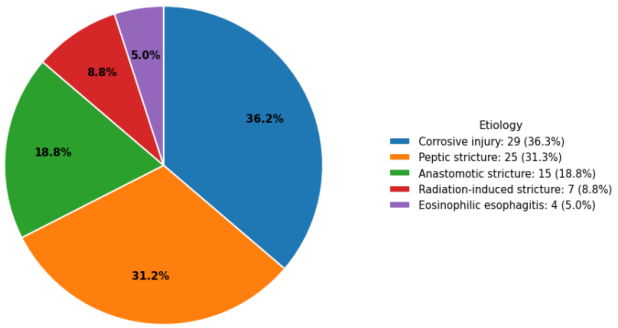

Figure 1. Etiology of Benign Esophageal Strictures

Figure 1. Shows distribution of benign esophageal stricture etiologies among the study population. Corrosive injury was the leading cause (36.3%), followed by peptic strictures (31.3%).

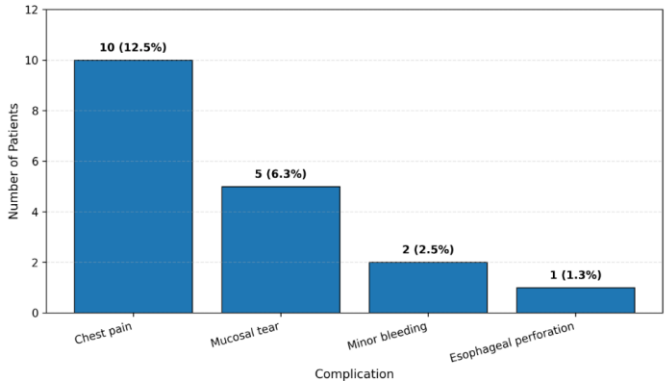

Figure 2. Procedure-Related Complications Following Serial Endoscopic Dilatation

Discussion

This study aimed to assess the safety and effectiveness of serial endoscopic dilatation in the treatment of benign esophageal strictures, and it showed high success rates both technically and clinically, and encountered only a few major complications. Technical success rate was 97.5% and improvement in dysphagia was seen in 92.5% of patients. These findings confirm that the second line of treatment for benign esophageal strictures should be serial endoscopic dilatation (SED), and agree with the current international literature, which reports technical success rates over 90% for the procedure performed by any experienced endoscopist.[16]

One of the significant observations of this study was that corrosive esophageal stricture was the most common (36.3%) and peptic was the second most common (31.3%). This distribution is different from that reported from Western countries where peptic strictures are less common owing to the use of proton pump inhibitors (PPI) in large numbers, whereas the

proportion of postoperative and radiation induced strictures has steadily increased and is now a large part of benign esophageal strictures.[17] Conversely, there are reports in other developing countries and regions that corrosive ingestion is still a major cause of benign esophageal narrowing because of increased availability of corrosive materials in the home and a delay in the provision of appropriate medical care. These regional disparities underscore the need to implement prevention and management measures based on the epidemiology in each area.

One of the most clinically relevant outcome measures of the present study was the marked improvement of dysphagia scores following serial dilatation. Satisfactory swallowing function is directly and immediately linked to better nutritional status, quality of life and psychological health. Patients had a mean reduction of the dysphagia score (Mellow-Pinkas) from 3.3 to 1.1, indicating significant symptomatic improvement. Pereira-Lima et al. also noted that long-term symptom-free after prolonged endoscopic dilatation was achieved in most benign stricture patients when they successfully dilated the lumen to an adequate size and maintained dilator patency by regularly revisiting the stricture endoscopically.[18] The results corroborate the notion that serial dilatation over a period of time is a more effective intervention for symptom control over a longer period of time when compared to a more aggressive single session.

In our study the average number of dilations of 3 is similar to previous reports. However, corrosive injury or postoperative fibrosis invariably produces a complex stricture that usually necessitates multiple sessions of treatment as it is difficult to immediately expand the esophageal lumen because of dense fibrosis. Repici et al. highlighted that repeated controlled dilatation sessions can prevent excessive trauma to the tissue while maintaining progressive remodeling of fibrotic tissue to prevent perforation without affecting clinical outcomes.[19] The individualized treatment schedule is still relevant since the length, diameter, etiology and patient responsiveness to therapy determine how many sessions are needed.

In our patients, dysphagia recurred in 15% who had to be treated again. While recurrence is an accepted weakness of endoscopic therapy, the rate seen in our study is similar to the literature, which has reported rates between 10% and 40% based on varied etiology and follow-up duration.[20] Due to scar contracture and fibrosis, corrosive and radiation induced strictures are especially likely to recur. Recurrent narrowing can be significantly decreased with long-term acid suppressing medications for peptic strictures, dietary changes for eosinophilic esophagitis and careful follow-up after surgery. Temporary fully covered self-expanding metal stents and intralesional steroid injections may further enhance long-term outcomes in patients with refractory disease.

The most important issue while performing esophageal dilatation is the risk of perforation, which can be life-threatening. Procedure-related complications were uncommon, with most being minor, for the present study. Chest pain and superficial mucosal tears were the most common adverse events, and only a single patient (1.3%) suffered from esophageal perforation. There were no deaths related to the procedure. The results are similar to those found in large multicenter studies, which consistently show that perforation rates are kept below 2% when using gradual dilatation technique and standardised procedural protocols.[21] In selected complex cases, patient selection, fluoroscopic guidance, avoidance of excessive force, and post-procedure monitoring are all crucial to safe endoscopic practice.

Improvements in endoscopic technology and gaining experience by operators also contribute to the excellent technical success seen in this study. The modern through-the-scope balloon dilators allow for controlled radial dilation with predictable pressures, while Savary-Gilliard bougies are still very effective at dilating selected fibrotic lesions. Grooteman et al. carried out a systematic review that found that both balloon and bougie dilatation are equally effective and have the same incidence of complications, and the choice of technique is based on anatomical factors and endoscopist experience, and not on which technique is superior.[22] This reinforces our methodology of using an individual approach in our institution with selection of dilator depending on the morphology of the stricture and the operators' judgment.

One of the major advantages of this study is the prospective assessment of efficacy and safety based on the standardised clinical criteria. Overall assessment of technical success, dysphagia improvement, recurrence and complications is possible simultaneously, enabling a thorough assessment in routine clinical practice. In addition, there were multiple benign etiologies, a reflection of the diversity seen in tertiary care centres, and therefore further enhancing the clinical applicability of the results. The higher incidence of corrosive strictures, however, might have had a bearing on the recurrence rates and number of treatment sessions required, as compared to populations in which peptic predominates.

There are also a number of restrictions that need to be noted. The study was carried out in a single tertiary care center and the sample size was relatively

small, thus the findings may be limited in generalizability. The follow-up period was short and no assessment of very long-term recurrence and sustained symptom relief was possible. Moreover, due to the small number of patients in each group, there was no subgroup analysis based on the etiology, length or the technique of dilatation for the strictures. Further multicenter trials with larger numbers of patients, longer follow-up, and the inclusion of comparative arms of intralesional corticosteroid, mitomycin-C, and temporary esophageal stents would yield more evidence for optimizing the treatment for troublesome benign esophageal stricture. [23,24]

In conclusion, the results of the present study are encouraging in favor of serial endoscopic dilatation as a very effective and safe treatment option for BES. Good symptomatic improvement with a low incidence of serious complication can be obtained by careful patient selection and following a standard dilatation protocol, treatment of the underlying etiology and regular follow-up. These findings support ongoing international guidelines that endoscopy-guided dilatation should be used as the mainstay of treatment in cases of symptomatic benign esophageal narrowing.

Conclusion

SED is a safe, effective and less invasive treatment option for patients with benign esophageal strictures. The current study showed high technical and clinical success rates and that swallowing function and dysphagia were significantly improved after serial dilatation. A favorable response to treatment, both in terms of symptom relief and the incidence of major complications such as esophageal perforation, was seen after a few sessions of treatment. The recurrence rate (2.4%) was low although a small number of patients did require further dilations, the results were good and this technique was recommended as the first line of treatment for benign esophageal narrowing. Optimal long term clinical outcomes and to mitigate procedure-related complications, it is crucial to employ a standardised dilatation protocol and to perform regular follow-up.

Recommendations

The results of the present study suggest that SED should continue to be the first-line therapeutic modality for symptomatic BES, because of its excellent efficacy and safety, and to be reserved for cases that are refractory to other therapies. Prompt referral for endoscopic evaluation and intervention is advised to prevent the progression of dysphagia, nutritional problems and complications of long obstructive symptoms. Patients should receive a personalized dilatation schedule, which should depend on the etiology, length, severity, and response to treatment of the strictures. Long-term follow-up should be ensured, particularly for patients with corrosive, radiation-induced, or anastomotic strictures, as these groups carry a higher risk of recurrence. Management should also focus on controlling the underlying cause of stricture formation, including optimal acid suppression for peptic strictures and appropriate medical or dietary therapy for inflammatory conditions such as eosinophilic esophagitis. Further multicenter prospective studies with larger sample sizes and longer follow-up are recommended to identify predictors of recurrence and to evaluate the role of adjunctive therapies, including intralesional corticosteroids, mitomycin-C application, and temporary stent placement, in patients with refractory benign esophageal strictures.

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