ORIGINAL ARTICLE

OESOPHAGEAL DILATION FOR STRICTURES: A PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY CARE HOSPITAL OF PAKISTAN

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Background: Oesophageal strictures pose a significant clinical challenge, requiring effective management to alleviate symptoms and improve the patient's quality of life. This study aimed to determine the effects of oesophageal dilation on patients with oesophageal stricture in terms of clinical improvement of dysphagia. **Methods:** This was a prospective, single-arm observational cohort study. Consecutive patients diagnosed with oesophageal stricture at Pak-Emirates Military Hospital, Rawalpindi, between 1 August 2022 and 31 July 2023 were enrolled and followed through up to five dilatation sessions. Data on demographics, causes, types of dilators used, and clinical results were collected. Patients underwent multiple sessions of dilations through the wire guided push dilators (Savary-Gilliard) or through the scope (TTS) balloon dilators, depending on the type of strictures and need of sessions. The procedure was considered successful if there was an improvement in dysphagia. **Results:** Among the 82 patients diagnosed with oesophageal stricture, 45 (54.9%) were men and 37 (45.1%) were women with a mean age of 46.17±14.75 years. The most prevalent causes of ES were gastro-oesophageal reflux disease (peptic) and caustic injury with a frequency of 25 (30.5%) each, followed by Schatzki's ring (n=13; 15.9%). Eighty patients (97.6%) showed improvement in dysphagia following dilatation, while 2 (2.4%) were referred to thoracic surgery. Simple strictures predominated in men (40/45, 88.9%) and complex strictures in women (28/37, 75.7%). Bleeding was the only complication recorded; it was more frequent in women and rose from 7.3% at the first session to 42.9% at the fifth. **Conclusions:** Up to five endoscopic sessions were performed at one- to two-week intervals using three dilator types. Most strictures were dilated to 15 mm or more. Only two patients, both with complex strictures, had persistent dysphagia after five sessions and required referral for surgical assessment.

Keywords: Dilation; Oesophageal stricture; Dysphagia; Gastro-oesophageal Reflux Caustic injury

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INTRODUCTION

Oesophageal stricture is an uncommon condition characterised by abnormal narrowing of the oesophageal lumen.[1] Typically, the oesophagus loses its natural elasticity as strictures form, which may occur either locally or diffusely along its length.[2] The annual occurrence rate of ES is approximately 1.1 per 10,000 person-years, with a noted correlation with advancing age.[1,3] An oesophageal stricture (ES) can be categorized according to its benign or malignant nature and its presentation as either a simple or complex stricture. Simple strictures typically exhibit a symmetrical and concentric shape, with a diameter of ≥12 mm, enabling the passage of a diagnostic endoscope. In contrast, complex strictures lack one or more of these characteristics, being asymmetrical with a diameter ≤12 mm, and may not permit the passage of a diagnostic endoscope.[4] Among adults, peptic stricture predominates, constituting approximately 70–80% of oesophageal stricture cases, often stemming from longstanding gastro-oesophageal reflux disease (GERD).[1,2,5] Moreover, it can be identified through a barium swallow, but the preferred diagnostic method is upper GI endoscopy, considered the gold standard. In some cases, an endoscopic biopsy of the lesion is necessary to determine its nature.[6]

Dysphagia, or difficulty in swallowing, is the predominant symptom, and arises when a stricture, whether benign or malignant, obstructs more than 50% of the oesophageal lumen.[7] Dysphagia, especially in its severe form, significantly affects a patient's ability to perform daily activities. It can also lead to malnutrition and increases the risk of aspiration, so prompt assessment is very important. Dysphagia can be

with solids, liquids or both; progressive or intermittent; and structural or non-structural.[8] Endoscopic dilation is the preferred treatment for benign oesophageal strictures. However, the optimal dilation technique and the types of strictures that can be effectively treated are still debated. Endoscopic dilation is generally the initial treatment, with surgery reserved for patients in whom dilation fails to relieve dysphagia adequately.[9] Three types of dilator are currently employed: wire-guided Savary-Gilliard bougies, through-the-scope endoscopic balloon dilators, and non-wire-guided mercury- or tungsten-filled push dilators (Maloney or Hurst).[10] Among these, Savary-Gilliard dilation is acknowledged as an efficient technique. Possible complications linked to dilation encompass perforation and bleeding. Major adverse events are rare, occurring in less than 1% of patients undergoing dilation sessions (either bougie or balloon dilation), with perforation reported in 0.5% of cases.[11]

For the past three decades, the "rule of three" has been enforced to avoid overly aggressive dilation and reduce the risk of adverse events. This guideline involves limiting dilations to an increase in lumen diameter of no more than 3 mm per session or day. However, adhering to this rule has led to an increase in the number of required endoscopic dilations and associated healthcare costs.[11] Furthermore, the aim of oesophageal dilation in individuals with oesophageal stricture is to achieve clinical success or enhance food intake. Most studies on oesophageal dilation consider successful treatment as lengthened intervals between dilations and enhanced tolerance of food intake.[12] Although oesophageal dilatation is widely used, its effect on dysphagia is inconsistently reported, and data from Pakistani tertiary-care practice are limited. This study was therefore undertaken to document the degree of symptomatic improvement achieved across successive dilatation sessions, the stricture diameters reached, and the complications encountered.

MATERIAL AND METHODS

This was a prospective, single-arm observational cohort study conducted in the gastroenterology department of Pak-Emirates Military Hospital (PEMH), Rawalpindi, from 1 August 2022 to 31 July 2023. 82 consecutive eligible patients were enrolled by non-probability consecutive sampling and were followed through up to five dilatation sessions. The primary outcome was improvement in dysphagia, graded at each session as able to eat a normal diet, tolerating thick liquids but not solids, tolerating a soft diet, or no improvement. Secondary outcomes were the stricture diameter achieved and post-procedure complications. There was no comparison group. Following the American Society of Anaesthesiologists (ASA) guidelines, patients in the study ceased intake of clear liquids for at least two hours and refrained from consuming light meals for a minimum of six hours before sedation administration. Aspirin and nonsteroidal anti-inflammatory drugs were not stopped. The approach to managing non-aspirin antiplatelet and anticoagulant therapy was tailored to each patient, based on the prescribing subspecialist's recommendation. Oesophageal dilation was conducted as an outpatient procedure under monitored anaesthesia care.

For simple oesophageal strictures, we adhered to the "rule of three," limiting balloon dilations to one or two millimetres per session. However, in some cases, we exceeded this limit for selected patients, such as those experiencing complete stricture recurrences after initial dilation. Endoscopic sessions for complex stricture patients were spaced one to two weeks apart to achieve a lumen diameter exceeding 13 mm. Once a lumen size greater than 13 mm was achieved, we increased the intervals between endoscopic sessions to more than two weeks. In each subsequent session, we began with the largest dilator used in the previous session. We did not use non-wire-guided push dilators (Maloney dilators) for complex strictures. Few patients were managed using a combination of dilators. All adults with dysphagia for solids and/ or liquids or both were included in this study. Those under the age of 18 who suffered from an acute or partially healed oesophageal perforation were excluded from this study. Exclusion criteria were a platelet count of less than 50,000/µL or an international normalized ratio >1.5, hemodynamic instability, the presence of malignant oesophageal stricture and who had recent gastric or oesophageal surgery. The exclusion criteria are designed considering the patient safety and to protect patients from risks such as perforation, bleeding, or complications.

The patient was positioned in the left lateral decubitus position. A gastroscope was inserted through the patient's mouth and advanced, under direct visualization, examining the appearance of the oesophageal mucosa and any strictures. The initial dilator size was chosen based on the estimated diameter of the stricture, which

was assessed by comparing it to the outer diameter of the gastroscope (9 mm). For example, if the estimated stricture diameter was 12 mm, the initial dilator size selected was 12 mm (36 French). The procedure involved the use of two types of dilators:

a. Wire-guided push dilators; such as the Savary-Gilliard: Once the endoscope's tip was positioned, the guidewire's tip was advanced through the endoscope's accessory channel and then advanced across the stricture. The endoscope was then withdrawn while keeping the guidewire in place, serving as a monorail for the dilator. The dilator was threaded over the guidewire and used to dilate the stricture. The resistance to passage and presence of blood on the dilator was assessed to determine the need for further dilation.
b. TTS balloon dilators; The stricture was located using upper endoscopy, and the balloon dilator was inserted through the biopsy channel of the endoscope, then advanced into the stricture under direct visualization. The balloon was inflated and maintained for 60 seconds. If the balloon could be moved freely through the stricture, its diameter was increased. Following dilation, the balloon was deflated and removed.

Wire guided push dilators such as Savary–gilliard was commonly used for their simplicity and effectiveness, particularly for less severe benign and non-circular long strictures. Balloon dilators were preferred where controlled dilation was required, particularly in tight or angulated strictures. Malignant strictures were excluded from this study. After the procedure, patients were monitored for recovery from sedation, permitted to drink water, and discharged with written dietary instructions based on the outcomes of the dilation procedure. The protocol of the study was approved by the research ethics committee of the institution.

Statistical analysis was performed using SPSS version 27.0.1. A *p*-value <0.05 was considered statistically significant. Continuous variables were summarized using mean and standard deviation, while categorical variables were presented as numbers and percentages. The relationship between categorical variables was assessed using the Chi-squared test. Additionally, multivariate logistic regression analyses were conducted to estimate odds ratios for each predictor and their impact on the likelihood of improvement in dysphagia.

RESULTS

Out of 82 patients, there were 45 (54.9%) male and 37 (45.1%) female patients, with a mean age of 46.17±14.75 years. Simple strictures were dilated in 49 patients (59.8%) and complex strictures in 33 (40.2%). The most common causes of oesophageal stricture were caustic injury (30.5%) and gastro-oesophageal reflux disease (30.5%), followed by Schatzki's ring (15.9%). All the parameters are expressed in Table 1.

Clinical manifestations of oesophageal stricture were also examined, with dysphagia for solids being the most prominent symptom (42.7%), accompanied by weight loss, heartburn, and odynophagia in varying combinations (Table 2).

Table 3 illustrates the clinical outcomes of oesophageal dilatation sessions. The predominant dilator utilised across all sessions was wire-guided polyvinyl dilators (Savary Gilliard or American). In the initial dilatation session, a stricture diameter of 18 mm or more was achieved in 34 patients (41.5%), and a diameter of 15 mm or more in 59 patients (72.0%). Additionally, 35 (42.7%) patients experienced an improvement in dysphagia, enabling them to consume a normal diet. Bleeding was the only post-dilatation complication recorded. Its frequency increased with successive sessions, from 6 of 82 patients (7.3%) at the first session to 9 of 52 (17.3%), 10 of 29 (34.5%), 8 of 20 (40.0%) and 3 of 7 (42.9%) at the second to fifth sessions respectively. No perforation occurred. Further, thirty patients achieved successful dilation following the first oesophageal dilatation session, while the remaining underwent multiple sessions as per needed. Only 2 patients out of the 82 were referred for thoracic surgery due to persistent lack of improvement even after the fifth dilatation session.

Outcomes differed markedly by sex. Complex strictures were present in 28 of 37 women (75.7%) compared with 5 of 45 men (11.1%), an unadjusted odds ratio of 24.89 (95% CI 7.53–82.23, p<0.001). At the first session, dilation to a diameter of 18 mm or more was achieved in 32 of 45 men (71.1%) compared with 2 of 37 women (5.4%), an unadjusted odds ratio of 43.08 (95% CI 9.02–205.82, p<0.001) (Table-4). Because women carried the great majority of complex strictures, sex and stricture complexity cannot be separated in this sample, and neither association should be read as independent of the other. Multivariable modelling of dysphagia improvement was not performed: the number of patients without improvement fell from 14 at the first session to 8, 1, 0 and 0 at the second to fifth sessions, which is insufficient to support a model containing five predictors and, from the third session onward, produces complete separation.

Table-1: Demographic and clinical parameters of patients

Parameters		Frequency (n)	Percentage (%)
Mean age (Mean±SD), years		46.17±14.75	
Age group	20-45	39	47.6
	46-65	38	46.3
	66-85	5	6.1
Gender	Male	45	54.9
	Female	37	45.1
Type of stricture	Simple	49	59.8
	Complex	33	40.2
Causes of oesophageal stricture	Caustic injury	25	30.5
	Gastro-oesophageal reflux disease (peptic)	25	30.5
	Schatzki's ring	13	15.9
	Radiation therapy	9	11
	Oesophageal surgery	4	4.9
	Others	6	7.3

Table-2: Symptoms of oesophageal stricture

Manifestations	Frequency (n)	Percentage (%)
Dysphagia for solids	35	42.7
Dysphagia for solids, Heartburn	23	28
Dysphagia for solids, Odynophagia	1	1.2
Dysphagia for both solids and liquids	10	12.2
Dysphagia for solids, Weight loss (>5% over 6 to 12 months)	3	3.7
Dysphagia for solids, Odynophagia, Heartburn, Weight loss (>5% over 6 to 12 months)	1	1.2
Dysphagia for solids & liquids both, Odynophagia, Weight loss (>5% over 6 to 12 months)	9	11

Table-3: Outcome of patients treated by endoscopic dilation

Clinical parameters		1st session n (%)	2nd session n (%)	3rd session n (%)	4th session n (%)	5th session n (%)	*p*-value
		(n=82)	(n=52)	(n=29)	(n=20)	(n=07)	
Dilation method	Balloon dilators	18 (22.0)	10 (19.2)	2(6.9)	0	0	>0.05
	Savary-Gilliard	61 (74.4)	40 (76.9)	27 (93.1)	20 (100)	7(100)	
	Mercury or tungsten-filled bougies (Maloney or Hurst)	3 (3.66)	2 (3.8)	0	0	0	
Stricture dilation (mm)	<13	13 (15.9)	7 (13.5)	1 (3.4)	0	0	<0.01
	13-14	10 (12.2)	9 (17.3)	8 (27.6)	4 (20)	2 (28.6)	
	15-17	25 (30.5)	15 (28.8)	14 (48.3)	13 (65)	5 (71.4)	
	≥18	34 (41.5)	20 (38.5)	6 (20.7)	3 (15)	0	
Dysphagia improvement	Able to eat normal diet	35 (42.7)	19 (36.5)	6 (20.7)	3 (15)	2 (28.6)	<0.01
	Allow for thick liquid but not solid food	8 (9.8)	11 (21.2)	8 (27.6)	3 (15)	0	
	Intake of soft diet	25 (30.5)	14 (26.9)	14 (48.3)	14 (70)	5 (71.4)	
	No improvement	14 (17.1)	8 (15.4)	1 (3.4)	0	0	
Post procedure complications	Bleeding	6 (7.3)	9 (17.3)	10 (34.5)	8 (40)	3 (42.9)	>0.05
Proceeded to a further session		52 (63.4)	29 (55.8)	20 (69.0)	7 (35)	2 (28.6)	<0.01

Table-4: Unadjusted association between sex and first-session outcomes

Outcome at first session	Men (n=45)	Women (n=37)	Odds ratio (95% CI)	*p*-value
Complex stricture	5 (11.1%)	28 (75.7%)	24.89 (7.53–82.23)*	<0.001
Dilation achieved to ≥18 mm	32 (71.1%)	2 (5.4%)	43.08 (9.02–205.82)†	<0.001

Odds ratios are unadjusted, with 95% confidence intervals from the Woolf method and p-values from Fisher's exact test. *Odds of a complex stricture in women relative to men. †Odds of achieving a diameter of ≥18 mm at the first session in men relative to women. Multivariable modelling was not performed; see text.

DISCUSSION

Oesophageal stricture presents a significant challenge, impacting the quality of life for patients. The associated primary and frequent complication is the inability to thrive due to compromised food intake. Hence its treatment usually includes dilating or widening the narrowed area. This can be accomplished through various methods such as balloon dilatation, bougie dilation, or stent placement. In severe cases, surgery may be necessary to remove the damaged portion of the oesophagus and reconstruct it. This study has been conducted to assess the impact of dilation on patients with oesophageal stricture, focusing on the clinical improvement of dysphagia.

In this study, the mean age was 46.17±14.75 years, with 54.9% male and 45.1% female patients.

Contrarily, Benites-Goñi *et al*.[4] reported an average age of 60.88 years wherein 67% were female and 33% were male. Similarly, studies conducted by Ahmad *et al*.[6], Khan *et al*.[13] determined mean ages of 35 and 26.72 years, with 66.1% females and 78.7% females respectively. Faizan *et al*., however, reported a mean age of 36.67 years, and the majority population in their study was of males (58.33%)[9]. For managing benign oesophageal strictures, endoscopic dilatation is a safe and successful option. It is replacing invasive surgeries, with higher morbidity and death rates and is generally considered as the first line of therapy. In this cohort, caustic and peptic strictures were equally common at 25 cases each (30.5%), while Schatzki's ring and radiation-induced strictures were less frequent. Since peptic strictures account for the vast majority of oesophageal strictures, the available literature focused exclusively on their dilatation approaches. There was a study which recruited 369 patients and found that peptic strictures made up to 63.7% of the cases and corrosive strictures made up 1.6%.[14]

In some of the patients, treatment of benign oesophageal strictures posed challenges and required considerable time and effort. Multiple dilatation sessions were often necessary to effectively manage these strictures and prevent their recurrence. In this study, a total of five dilatation sessions were performed. However, the number of patients undergoing subsequent sessions decreased, with only 20 and 7 patients undergoing the fourth and fifth sessions, respectively. These findings were consistent with Isa *et al*., who reported that 21 patients, constituting 80.7% of the cohort, needed more than one dilatation session. Patients with severe strictures generally needed regular dilatations than those with mild strictures.[10] Additionally, Cakmak and his co-workers noted that corrosive strictures, in particular, required dilation sessions that took longer time and multiple sessions as compared to anastomotic strictures.[19] Faizan *et al*. found that in Pakistani population, 61 (50.83%) patients had achieved adequate dilation, with 20% of the study cohort undergoing 1–2 sessions of dilation and 30 (26.7%) patients requiring more than four sessions.[9]

In the current study, out of 37 female patients, 28 (75.7%) presented with complex strictures. Whereas 11.1% men had complex strictures. As far as the success of the procedure is concerned, 32 (71.1%) out of 45 men achieved dilation of stricture >18 mm and the frequency in women was 2 (5.4%) after the first dilatation session. Eighty of the 82 patients had improvement in dysphagia. Bleeding was the only complication observed, and its frequency rose across successive sessions. Ahmad *et al*. reported that in their study, perforation (0.5–1.2%) was the most common complication seen with endoscopic oesophageal dilatation. Other complications were haemorrhage and bacteraemia. They also inferred that the risk of perforation and bleeding was higher with complex strictures compared with simple strictures.[6] In the present cohort, bleeding was more frequent in women than in men, consistent with the higher proportion of complex strictures among women. Complex strictures are more difficult to dilate and carry a greater risk of perforation, although no perforation occurred in this series.

Study Limitations

Similar to other research, this study has several limitations including the relatively small sample size, which had limited the generalizability of the findings. Secondly, the study was subjected to selection bias, as it was conducted at a single centre. Thirdly, the short follow-up period was one of the critical drawbacks, as longer-term outcomes of the treatment were not fully assessed. Lastly, the study lacked a control group for comparison, which restricted the ability to draw definitive conclusions about the effectiveness of the treatment. Further studies must focus on multi-centre, long-term research encompassing various diverse populations to highlight the causes and suggest potential remedies for oesophageal strictures allowing better generalizability of findings.

CONCLUSION

To conclude, most oesophageal strictures were effectively dilated to a diameter of 15 mm or more over a maximum of five endoscopic sessions at one- to two-week intervals. Some patients, particularly those with complex strictures, continued to experience dysphagia despite five sessions and required further intervention. Oesophageal strictures that remained unresponsive to five endoscopic dilation sessions were classified as refractory strictures, prompting referral to a thoracic surgeon for evaluation and consideration of surgical treatment. This study can have significant broader implications for clinical practice, particularly in resource-limited settings, by demonstrating that effective treatment of oesophageal strictures is achievable with minimal equipment, cost, and specialized training. The research can empower healthcare providers in under-resourced areas to manage oesophageal strictures effectively, improving patient outcomes, reducing healthcare costs, and expanding access to care for vulnerable populations.

Conflict of Interest

None

AUTHORS' CONTRIBUTION

AS, RH, RSAK: Data collection, write up, Literature review. JK, NI: Data analysis, proof reading, literature review. NG: Writing of manuscript, supervised the study.

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