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ORIGINAL RESEARCH

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Pneumatic dilation for the treatment of persistent post-laparoscopic fundoplication dysphagia: long-term efficacy and safety

Paraskevas Gkolfakis, Diane Lorenzo, Daniel Blero, Hubert Louis, Arnaud Lemmers, Marianna Arvanitakis, Pierre Eisendrath and Jacques Devière

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ABSTRACT

Background: Post-laparoscopic fundoplication (LF) dysphagia occurs in 5%–17% of patients and optimal management remains a topic of expert discussion. We assessed the efficacy and safety of pneumatic dilation (PD) in patients with persistent post-lLF dysphagia.

Methods: Medical files of patients treated with PD for persistent post-fundoplication-associated dysphagia were reviewed. The primary outcome was long-term clinical success. Secondary endpoints were initial clinical success, dysphagia recurrence rate, and PD-related complication incidence.

Results: Overall, 46 patients (74% women, 57.9±11.9 years) underwent 74 PD (mean: 1.6±0.8). A 30 mm, 35 mm, and 40 mm balloon was used in 45.9%, 43.2%, and 10.8%, respectively, of dilations. Among 45 patients with available follow-up, the overall long-term success rate of PD was 31/45 (68.9% [55.4–82.4]). Initial clinical success was 36/45 (80% [68.3–91.7]). Dysphagia recurred in 9 patients (25%; 95%CI 10.9–39.1) and 4 of these were effectively treated with a new dilation. Among 14 non-responders to PD, 11 underwent surgery. Four complications (2 perforations, 1 muscularis dilaceration, and 1 peri-procedural bleeding) occurred in 4 patients (incidence: 5.4% [95%CI; 0.3–10.6]) and were treated with partially covered self-expandable esophageal stents andhemostatic clips.

Conclusions: Pneumatic balloon dilation for post-fundoplication-associated symptoms is associated with a satisfactory long-term success rate and acceptable safety profile.

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Laparoscopic fundoplication; dysphagia; pneumatic dilation; endoscopy; nissen

1. Introduction

Laparoscopic fundoplication (LF), with or without hiatal hernia repair, is considered the standard of care for the long-term treatment of patients with symptomatic gastro-esophageal reflux disease (GERD)[1]. It is indicated for patients who do not respond to proton pump inhibitor (PPI) treatment, are not willing to follow a continuous PPI intake regimen or who carry risk factors of progressive diseases like nocturnal reflux, esophagitis, family history of GERD, or concurrent alcohol consumption [2,3]. Over the last three decades, LF has evolved into a minimally invasive surgical intervention with high success rates and very low peri-interventional morbidity. However, post-surgical side effects may occur [4,5]. The most common post-LF side effects are inability to belch or vomit, gas bloating, flatulence, and dysphagia, which can be explained by increased lower esophageal sphincter (LES) resting and residual relaxation pressures after LF that further inhibit gastric content reflux toward the esophagus[1].

Post-LF dysphagia can be further classified as early and persistent. Early dysphagia appears early post-operatively and is mainly attributed to coexistent postoperative edema. Its management consists of conservative treatments including adequate hydration and a liquid/soft diet and usually resolves within 12 weeks of surgery. On the other hand, dysphagia that persists for more than 3 months should be further evaluated with para-clinical examinations and is usually the result of a tight fundoplication wrap (tight crural closure), a slipped wrap, or a paraesophageal hernia[1].

Despite the fact that the incidence of post-LF dysphagia seems to be lower in patients undergoing partial posterior or anterior (Toupet or Dor) fundoplication compared to those undergoing a complete posterior fundoplication (Nissen)[6], cohort results demonstrate similar rates of dysphagia during long-term follow-up, independently of the technique that is used [7,8]. Overall, post-LF dysphagia rates vary between 5% and 17% in different series, remaining a pragmatic and existing concern in the care of these patients [4,9,10].

To date, specific recommendations regarding the management of post-LF dysphagia are lacking, but both hydrostatic and pneumatic dilations have been proposed as potential treatment approaches. However, the current evidence, from a series with either a small number of patients or a short follow-up period, suggests only moderate efficacy. Thus, we aimed to evaluate the natural history of patients with post-LF dysphagia treated by pneumatic dilation, focusing on its long-term efficacy and safety.

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2. Methods

2.1. Study design

This retrospective study was conducted at Erasme University Hospital in Brussels, Belgium. The study protocol was reviewed and approved by the local Ethics Committee (Ref. Nr.: P2020/291) which waived patient informed consent. The study data are presented according to the STROBE guidelines (**Appendix A**)[11].

2.2. Setting – participants- inclusion criteria

The medical files of all patients who underwent pneumatic dilation for the treatment of persistent (> 3 months) post-fundoplication-associated dysphagia from 1 January 2006 to 31 December 2019 were reviewed. To assess patients for eligibility, the endoscopy documentation system used in our department (Endobase, Olympus Medical Systems) was queried for the words 'fundoplication,' 'Nissen' and 'pneumatic dilation.' Symptomatic dysphagia, absence of fibrotic stenosis in upper gastrointestinal endoscopy, and treatment with at least one pneumatic dilation were inclusion criteria for the study. Patients undergoing pneumatic dilation for dysphagia related to other diseases (achalasia, post-sleeve gastrectomy stenosis) were excluded. Patient demographic and clinical characteristics as well as radiological and endoscopic data were collected through access to electronic hospital records. For patients referred or followed by a different department, an effort to contact the referral physician or the patient or their relatives was made to ensure the most accurate information regarding patient outcome. The final medical file review took place in June 2020.

2.3. Endoscopic interventions – patient follow-up

Pneumatic dilation was performed under general anesthesia with endotracheal intubation. Using a diagnostic gastroscope, a Savary guidewire was left in the antrum after confirming the absence of a fibrotic stricture throughout the esophagus and the gastroesophageal junction. While the endoscope was retrieved, the point of the fundoplication to be dilated was marked fluoroscopically, while contrast injection was used to further identify anatomical landmarks and assess for intrathoracic slipping of the fundoplication. Then, an achalasia balloon dilator (Rigiflex, Boston Scientific, Marlborough, MA) was advanced fluoroscopically with its middle radiopaque markers placed at the desired dilation point. The balloon was then inflated at the respective pressure, always under fluoroscopic control. In the case of early slippage into the stomach during dilation, the balloon was repositioned more proximally and re-inflated (Figure 1). The size of the balloon was left to the discretion of the endoscopist, but a 30 mm balloon dilator was usually used for the index dilation, while consecutive ones were performed with balloons of progressively increasing diameter (35 mm or 40 mm). The duration of dilation was decided on a case-by-case basis by the performing endoscopist and was usually

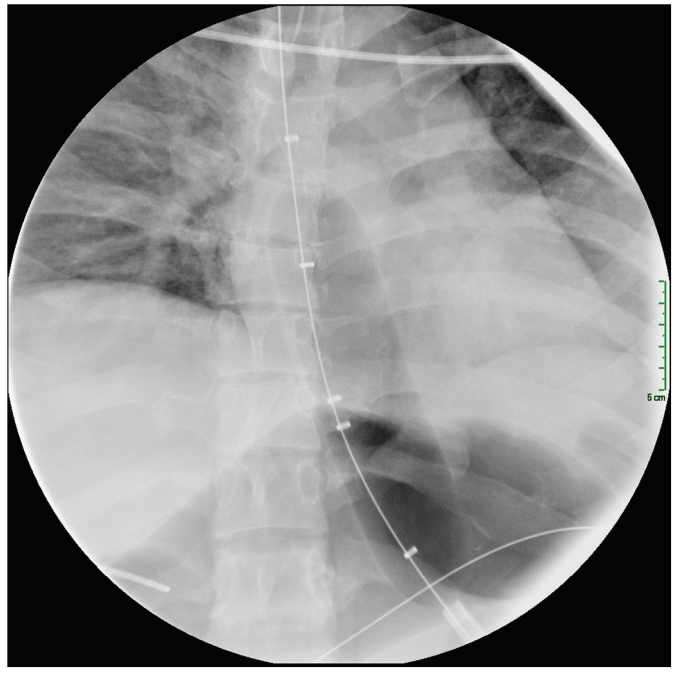

Figure 1. Pneumatic dilation for post-laparoscopic fundoplication dysphagia using a 30-mm achalasia balloon.

2 minutes. After that, the balloon was deflated and retrieved, and the site of dilation was controlled endoscopically for lacerations or bleeding, and fluoroscopically using contrast injection for perforation. Patients received intravenous proton-pump inhibitors for 24 hours and then according to their symptoms. They resumed a liquid diet the day after with progressive restoration of the normal diet (2–3 days). If no immediate complications were documented, patients were discharged within 24 hours after the procedure.

In our department, patients presenting with post-fundoplication dysphagia undergo a detailed pre-interventional work-up including upper gastrointestinal endoscopy, esophageal high-resolution manometry, and barium swallow study (Figure 2) in order to exclude any luminal or motility disorder. Based on the results of the examination and following consideration in the local multidisciplinary (MDT) meeting, a decision about the therapeutic approach is made. The patient is then followed in the outpatient clinic up to a year at trimonthly intervals to evaluate their response to treatment. During this 12-month endoscopic treatment period, additional pneumatic dilations may be performed according to the physician's judgment and tailored by patient symptoms. At the end of 12 months, patients having responded to the endoscopic treatment are discharged and followed annually with the advice to return early in case of dysphagia recurrence. If endoscopic treatment is considered inefficacious, the patient is further liaised with the foregut surgical clinic with consideration of fundoplication revision. In the case of recurrence, the patient is presented at the MDT meeting that evaluates eligibility for available therapeutic approaches including conservative treatment and follow-

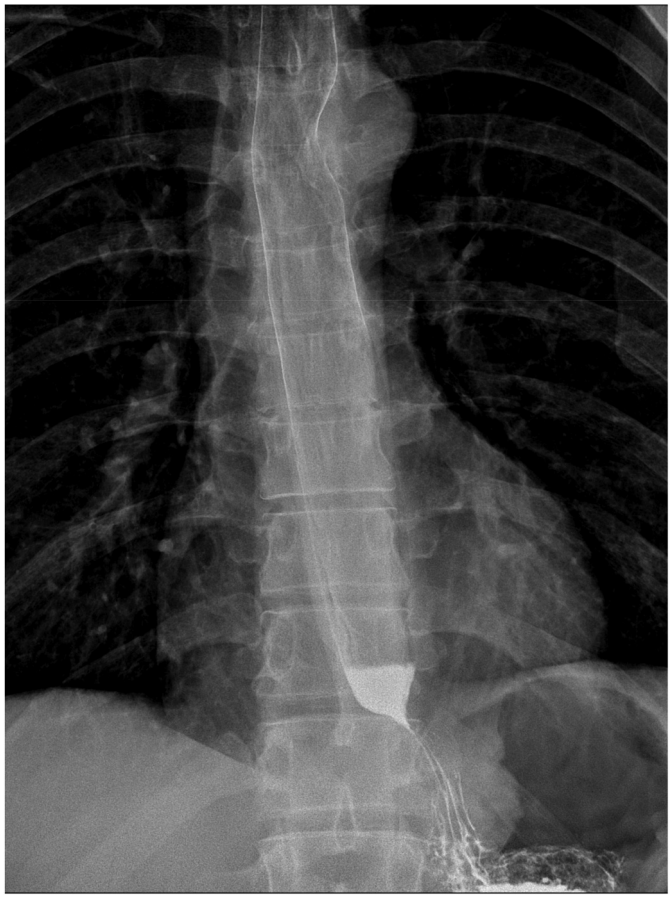

Figure 2. Swallow barium study demonstrating esophagogastric outflow obstruction with respective dilation of the esophagus.

up, repetition of endoscopic therapy (new pneumatic dilation session), or surgical treatment.

2.4. Primary endpoint

The primary endpoint of the study was to assess the long-term clinical success of endoscopic treatment defined as the resolution of post-LF-dysphagia at the end of the follow-up.

2.5. Secondary endpoints

The secondary endpoints of the study were to evaluate: (i) the initial clinical success of endoscopic treatment defined as symptom resolution at the end of the first 12-month treatment period, (ii) the dysphagia recurrence rate defined as dysphagia reappearance in patients having achieved initial clinical success and (iii) the safety of pneumatic dilation for the treatment of post-fundoplication dysphagia. Documentation of complications and severity grading was based on the adverse event lexicon proposed by the American Society of Gastrointestinal Endoscopy including perforation, bleeding, infection, and pain[12].

2.6. Statistical methods

Continuous variables are presented as means with standard deviation (SD) or median with interquartile range (IQR), depending on their distribution. Categorical variables are summarized as frequencies and proportions. The Mann–Whitney U-test and the chi-squared test were used as appropriate for comparisons. Univariate analysis using binomial logistic regression was used to identify factors that predicted symptom recurrence. Data were extracted in pre-specified Microsoft Office Excel data sheets (Microsoft Corporation, Richmond, WA) and analyzed using the Statistical Package for Social Sciences (IBM Corp. Released 2017. IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY: IBM Corp). Significance was set at a p-value of <0.05.

3. Results

Overall, 46 patients underwent at least one PD for post-LF symptoms. Table 1 depicts the baseline patient characteristics

Table 1. Patient baseline characteristics.

Sex, n (%)	
Male	12 (26.1)
Female	34 (73.9)
Age, years, mean (SD)	57.9 (11.9)
CCI, mean (SD)	2.1 (1.4)
Antithrombotic/antiaggregant agents, n (%)	
No	41 (89.1)
Yes	5 (10.9)
Weight, kg, mean (SD)	68.1 (16.1)
Manometry or/and barium swallow study, n (%)	
No	3 (6.5)
Yes	43 (93.5)
Manometry findings, n (%)	
EGJ outflow obstruction	12 (48)
Absent contractility	3 (12)
Inefficient esophageal peristalsis	4 (16)
Normal	6 (24)
Swallow study findings, n (%)	
Esophageal stenosis	18 (43.9)
Esophageal Dilation	11 (26.8)
Normal	8 (19.5)
Other	4 (9.8)
Intrathoracic slippage of Nissen, n (%)	
No	39 (84.8)
Yes	7 (15.2)
Indication for Nissen, n (%)	
GERD	29 (63)
Hiatus hernia	11 (23.9)
GERD and hiatus hernia	5 (10.9)
Gastric volvulus	1 (2.2)
Nissen Revision before PD, n (%)	
No	36 (78.3)
Yes	10 (21.7)
Previous endoscopic treatment, n (%)	
No	40 (87)
Yes	6 (13)
Type of previous endoscopic treatment, n (%)	
Hydrostatic dilation (18–20 mm)	4 (66.7)
Pneumatic Dilation (30–35 mm)	2 (33.3)
Other associated symptoms, n (%)	
Retrosternal pain	20 (43.5)
Regurgitation	17 (37)
Weight loss	14 (30.4)
Eckardt score before PD, mean (SD)	5 (1.8)

SD: standard deviation; CCI: Charlson Comorbidity Index; EGJ: esophagogastric junction; GERD: gastro-esophageal reflux disease; PD: pneumatic dilation

including demographics, pre-treatment evaluation, and clinical presentation. Among them, 34 (73.9%) were women and the mean age was 57.9 years, while 10 patients (21.7%) had already undergone a Nissen revision before their endoscopic treatment. Apart from dysphagia (mean Eckardt score 5 ± 1.8), other associated symptoms included retrosternal pain in 20 (43.5%) and regurgitation in 17 (37%) of the patients. Moreover, 6 (13%) of the included patients had undergone at least one previous endoscopic treatment at another institution, mainly a hydrostatic balloon dilation using controlled radial expansion balloons at 18–20 mm (4/6; 66.7%). Finally, all but three patients [43 (93.5%)] underwent esophageal manometry and/or barium swallow study with evidence of esophageal stasis or esophagogastric junction outflow obstruction.

Table 2 summarizes the characteristics of the endoscopic treatment. We performed 74 pneumatic dilations [median time from LF to first PD: 45 months (10.7–100.3)] with most patients undergoing either one [27 (58.7%)] or two [12 (26.1%)] dilations (mean dilation number per patient 1.6 ± 0.8). A 30 mm or 35 mm balloon was used in 34 (45.9%) and 32 (43.2%) of the procedures, respectively. In the majority of the patients [28 (60.9%)] the first dilation was performed using a 30 mm balloon, while the mean duration of the dilation was 2.4 ± 1.3 minutes.

Table 2. Characteristics of pneumatic dilations.

Total number of PD, n	74
Number of PD per patient, n (%)	
1	27 (58.7)
2	12 (26.1)
3	5 (10.9)
4	2 (4.3)
PD per patient, mean (SD)	1.6 (0.8)
Size of balloon, overall, n (%)	
30 mm	34 (45.9)
35 mm	32 (43.2)
40 mm	8 (10.8)
Size of balloon for the 1st PD), n (%)	
30 mm	28 (60.9)
35 mm	16 (34.8)
40 mm	2 (4.3)
Duration of PD, min, mean (SD)	2.4 (1.3)

PD: pneumatic dilation; SD: standard deviation

3.1. Primary endpoint

Figure 3 depicts the study flowchart. Overall, 45 patients had an available follow-up (median follow-up 665 days) and were considered eligible for analysis regarding the primary outcome. At the end of follow-up, the endoscopic treatment was considered successful in 31/45 patients leading to a long-term success rate (95%CI) of 68.9% (55.4–82.4); Table 3. The mean difference in the Eckardt score post- and pre-treatment was −3.55 points ($p < 0.001$). Among patients achieving long-term clinical success, the mean number of PD was 1.7 ± 0.9, while in 17 (54.8%) patients, long-term clinical success was achieved after a single dilation (10 [58.8%] patients at 30 mm and 7 [41.2%] patients at 35 mm).

3.2. Secondary endpoints

(i.) Initial clinical success: Thirty-six patients had a resolution of their symptoms at the end of the first year of follow-up, thus the initial success rate (95%CI) of the endoscopic treatment was 80% (68.3–91.7). The mean number of PD required to achieve initial clinical success was 1.5 ± 0.7 with 23 (63.9%) patients undergoing a single dilation and 10 (27.8%), 2 (5.5%), and 1 (2.8%) patients undergoing 2, 3, and 4 PD during the

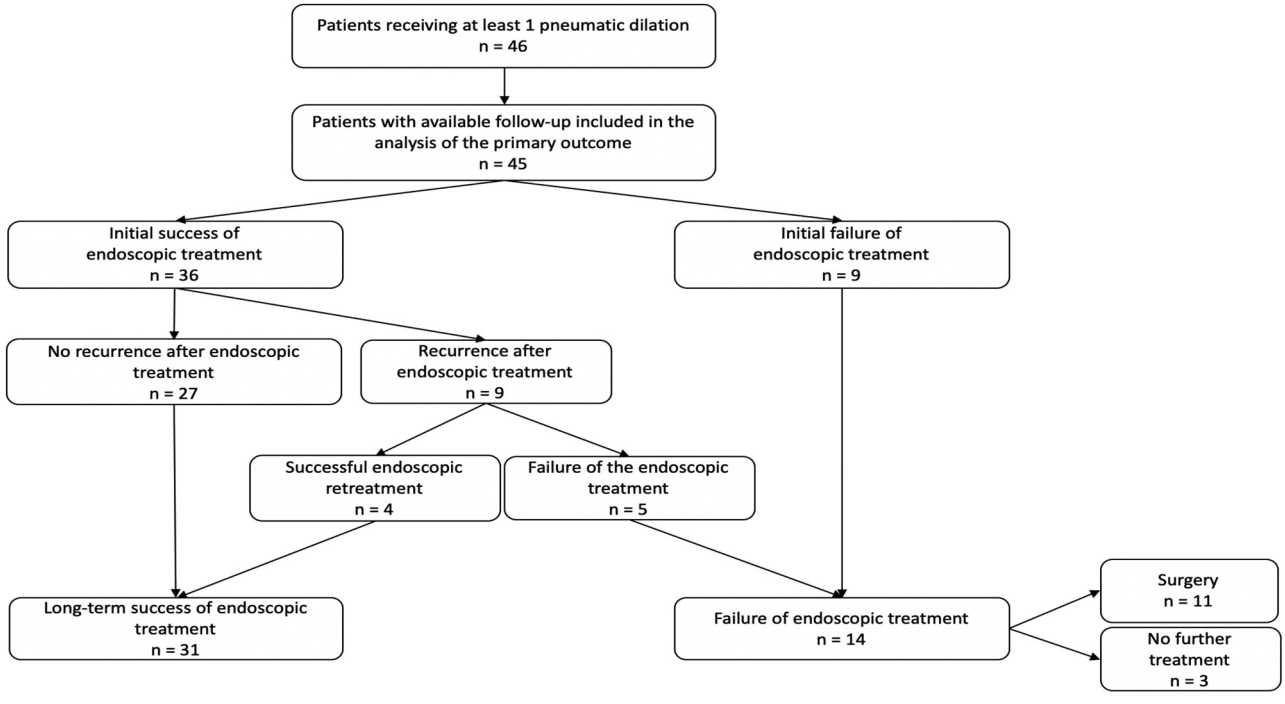

Figure 3. Study flowchart.

Table 3. Study outcomes.

Initial outcome of endoscopic treatment, n; (%, 95%CI)*	36; 80% (68.3–91.7)
Clinical success	9; 20% (8.3–31.7)
Failure	
Recurrence, n (%, 95%CI)*	9; 25% (10.9–39.1)
Long-term outcome of endoscopic treatment,, n; (%, 95%CI)*	31; 68.9% (55.4–82.4)
Clinical success	14; 31.1% (17.6–44.6)
Failure	
Eckardt score post PD*, mean (SD)	1.6 (1.2)
Mean difference (95%CI) in Eckardt score after and before PD	−3.55 (−4.19, −2.91); $p < 0.001$
Complication rate, % (95%CI)**	5.4% (0.3–10.6)
Type of complications, n	2
Perforation	1
Severe bleeding	1
Muscularis laceration	
Follow-up, days, median (25^{th}-75^{th} percentile)	681 (296–1647)

*Among the 45 patients with an available follow-up
**Among the 74 pneumatic dilations
PD: pneumatic dilation; CI: confidence interval; SD: standard deviation

first 12-months, respectively. Among the 23 patients requiring a single PD, a 30 mm and a 35 mm balloon was used in 13 (56.5%) and 9 (39.1%) of them, respectively.

(ii.) Dysphagia recurrence rate: During follow-up, 9 patients presented with symptom recurrence [25% (10.9–39.1)] and, after multidisciplinary decision, a new endoscopic treatment was offered to 5 of them with 4 of them responding favorably through the end of follow-up. For these 4 patients, the maximum balloon diameter required to treat dysphagia recurrence was 35 mm in 2 patients and 30 mm and 40 mm in 1 patient, respectively. Regarding the 14 patients where the endoscopic treatment was not considered efficacious, a surgical option was offered to all of them after multidisciplinary discussion. This proposition was accepted by 11 patients (7 after initial failure and 4 after symptom recurrence), whereas 3 patients decided to be followed clinically with dietary modification.

(iii.) Adverse event rate: Overall, in our cohort, 4 PD-related complications were recorded; thus, the complication incidence rate (95%CI) was 5.4% (0.3–10.6). As shown in Table 3, these four complications included 2 perforations, 1 muscularis intramural dilaceration, and 1 severe peri-procedural bleeding. The first perforation occurred after dilation at 30 mm at the level of the plication and the second one after dilation at 35 mm at the level of the lower esophagus (Figure 4A). Similarly, the muscularis dilaceration occurred also at the lower esophagus after dilation using a 35 mm balloon. These 3 cases were all effectively treated using large partially covered self-expandable metallic stents (Figure 4B; UltraflexTM, Boston Scientific, Marlborough, MA, USA) that were uneventfully removed 6–8 weeks later using the stent-in-stent technique. Finally, hemostatic clips were used to successfully stop the bleeding in the fourth case. None of the different patient- and endoscopic treatment-related factors (Nissen indication, slipped fundoplication, previous dilation, time between Nissen and 1^{st} PD, number of PD, size of first PD dilation, and Eckardt score) that were included in the univariable analysis was associated with the long-term success of the endoscopic treatment (data not shown). Finally, among all patients included in the analysis, a *de novo* post-treatment heartburn appeared in 6 of them [13.3% (3.4–23.3)].

4. Discussion

The optimal approach for tackling persistent post-laparoscopic fundoplication symptoms, predominantly dysphagia, remains a subject of expert discussion. In this retrospective cohort study of patients followed for a median period of 2 years, we demonstrated that pneumatic dilation is associated with a satisfactory long-term success rate and acceptable safety profile. Moreover, we showed that endoscopic re-treatment remains a reliable choice for individuals whose symptoms recur during follow-up.

The results of our study are in line with previous evidence derived from retrospective series. Sunjaya et al. [13] enrolled 38 patients with persistent (> 6 months) dysphagia post-LF whose previous treatment with Savary or hydrostatic dilation had failed. The response rate after a single PD (34/38 at 30 mm) was 44.7% but the follow-up period for this was

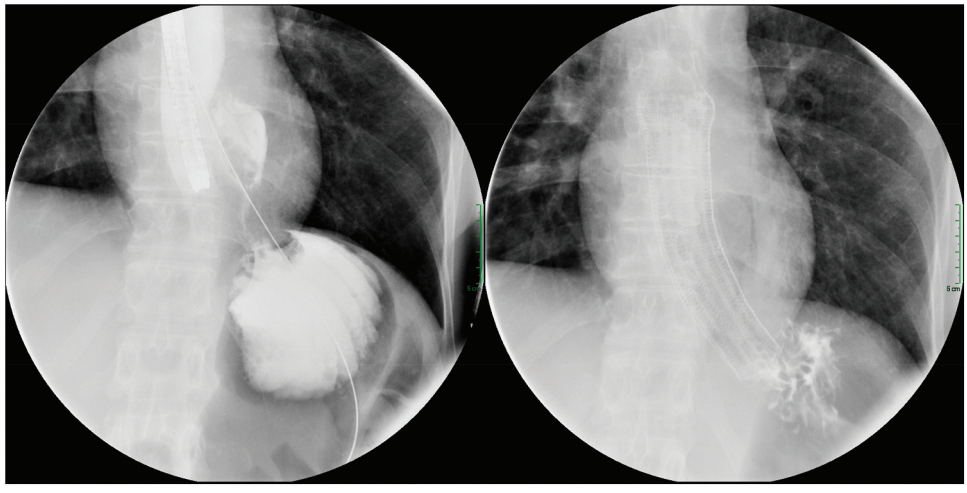

Figure 4. Perforation of the lower esophagus following dilation at 35-mm (A) effectively treated by partially covered self-expandable metallic stent.

limited to 28 days. In two earlier and smaller studies, the response rates were 64% and 56.3% [14,15], with both studies providing an additional second dilation if there was no response after the initial treatment. In these studies, patients were followed for a mean period of 9 and 19.2 months, respectively. More recently, a randomized controlled trial compared single PD at 35 mm versus sham procedure for 42 patients with persistent (> 3 months) dysphagia after antireflux surgery and found that PD was not superior since treatment success rates (measured as an Eckardt score < 4 with a minimal reduction of 2 points) at 30 days were 33% and 38% for PD and sham procedure, respectively[16]. The authors concluded that PD should not be offered in patients where there is no objective documentation of obstruction.

Indeed, patients presenting with post-LF symptoms should undergo a detailed work-up in order to exclude any motility or luminal pathology. In younger patients, esophageal biopsies to exclude eosinophilic esophagitis should also be performed as part of the standard pre-interventional evaluation, while assessment by an expert to rule out any functional disease remains crucial. In our institution, our approach to patients presenting with post-LF symptoms has evolved during the last 15 years and, at the present time, PD is offered to patients with signs of obstruction, either on high resolution manometry or in a barium swallow study. However, at the early stages of the study period, a minority of patients received PD based on symptom evaluation and the findings of an upper gastrointestinal endoscopy. For the sake of this study, we decided to include these patients (n = 3) in our analysis, aiming to depict, in the most accurate way, the real-life experience from a tertiary center throughout the last 15 years.

Available evidence on post-LF symptoms, including our results, should be viewed with caution since significant heterogeneity in inclusion criteria and outcomes may be detected. For example, different scores have been used to assess dysphagia, including the Eckardt score [17] that has been developed and validated in individuals with esophageal achalasia, while there is no score being tested in patients presenting with post-LF symptoms. Moreover, the resolution of the principal complaint is often used to determine the efficacy of the endoscopic treatment. Obviously, this approach includes an inevitable degree of subjectivity calling for cautious generalizability of the results.

Despite the fact that a 3-month cutoff is commonly used to define persistent dysphagia, in our cohort, a proportion of patients presented with new occurrence of dysphagia late after LF. This has been previously described[18], but, in our univariable analysis, the interval between the time of the surgery and the first PD did not affect the outcome. In any case, premature intervention should be avoided and patients should be provided with nutritional support, education, and close follow-up to detect symptom resolution.

Our institutional real-life experience suggests that alternative treatment for patients in whom endoscopic treatment fails is challenging. Surgical revision carries a morbidity risk and it is usually kept as a salvage therapy from the physician's point of view, and patients are also not always keen to accept such a proposition. Interestingly, in our cohort, 20% of patients with failure of endoscopic treatment remained reluctant to undergo surgical revision (3/14 patients; 2 after initial failure of endoscopic treatment and 1 after failure of retreatment after recurrence) preferring to receive only conservative treatment. On the other hand, antidepressants and hypnotherapy have been used in functional dysphagia, but available evidence on post-LF dysphagia is lacking, further narrowing the spectrum of available therapeutic options [19,20]. Under this prism, pneumatic dilation may prove to be treatment that significantly affects the quality of life for these patients, who often have few therapeutic options. Moreover, our study highlights the importance of long-term follow-up since almost half of the cases with symptom recurrence were successfully re-treated endoscopically.

As is true for all procedures in therapeutic endoscopy, endoscopists should be aware of potential complications following pneumatic dilation and be prepared to manage them. The most important amongst them is perforation. In our cohort, we experienced two cases of gastrointestinal perforation (and one intramural dilaceration) that were effectively treated with partially covered self-expandable stents. We strongly believe that partially covered stents are the most appropriate for avoiding early migration after such dilatation has been performed. It should be underlined that, compared to the chronically contracted and stiff lower esophageal sphincter in achalasia patients, the fundoplication structure consists of healthy tissues with normal elasticity making them more vulnerable to perforation. Thus, extreme caution should be taken, especially in the pre-intervention assessment (endoscopy, barium swallow study), to exclude the possibility of intrathoracic slipping of the fundoplication. In such a case, PD will also affect the lower esophagus, and lower esophageal sphincter and caution should be taken, never starting with a diameter larger than 30 mm.

Our study has some strengths that are worthwhile to mention. First, this is one of the largest cohorts in the literature aiming to elucidate outcomes of endoscopic treatment in this challenging group of patients. Moreover, a novel characteristic of our study is that it provides the longest follow-up after endoscopic treatment, allowing us not only to evaluate the long-term efficacy of the method but also to identify patients who recurred and assess the impact of a *de novo* pneumatic dilation. Finally, all therapeutic decisions were based on a patient-tailored approach after discussion in a dedicated multidisciplinary meeting permitting a homogeneous attitude for patient management.

We would like to acknowledge some limitations regarding our study. First, and as for all retrospective studies, a bias of adverse events underreporting cannot be excluded. Nevertheless, all patients were hospitalized for at least 24 hours after dilation; thus, we believe that all acute intervention-related adverse events have been documented. Second, we aimed to restrain the inevitable reporting bias, and obtain the most accurate information regarding patient follow-up, by not only assessing patient medical files but also contacting patient referring surgeons and general practitioners. Finally, the retrospective design of our study did not allow us to assess potential correlations between patients

outcomes and technical elements of the index operation (e.g. different type of fundoplication, intraoperative use and size of bougie, intraoperative use and type of mesh when concomitant hiatal hernia repair takes place). However, even if we believe that future prospective studies should also take these elements into account, our cohort represents the typical heterogeneous group of patients referred to a tertiary center for possible treatment.

5. Conclusion

In conclusion, this retrospective study of a prospectively built cohort suggests that pneumatic dilation can provide satisfactory results in the long-term resolution of post-LF-associated dysphagia with an acceptable safety profile. It should be offered within a patient-tailored approach to this difficult-to-treat group of patients after meticulous work-up excluding any motility or luminal pathology.

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Notes on contributor

P Gkolfakis and D Lorenzo acquired the data, performed the analysis, drafted the manuscript, and approved the final manuscript; D Blero, H Louis, P Eisendrath, and A Lemmers revised the draft critically for important intellectual content and approved the final manuscript; J Devière conceived the idea, revised the draft critically for important intellectual content, and approved the final manuscript. All authors agreed to be accountable for all aspects of the work.

Declaration of interests

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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Appendix

Appendix A. STROBE Checklist

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	3,4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4,5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	4–6
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6,7
Bias	9	Describe any efforts to address potential sources of bias	NA
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	
		(*d*) If applicable, explain how loss to follow-up was addressed	
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study – eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed	7,8 Figure 1
		(b) Give reasons for nonparticipation at each stage	
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7,8
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) Summarize follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	8–10
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8–10
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done – eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarize key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10–14
Generalizability	21	Discuss the generalizability (external validity) of the study results	10–14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	NA