Original research

Pneumatic dilation for persistent dysphagia after antireflux surgery, a multicentre single-blind randomised sham-controlled clinical trial

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ABSTRACT

Objective There is no evidence-based treatment for persistent dysphagia after laparoscopic fundoplication. The aim of this study was to evaluate the effect of pneumatic dilation on persistent dysphagia after laparoscopic fundoplication.

Design We performed a multicentre, single-blind, randomised sham-controlled trial of patients with persistent dysphagia (>3 months) after laparoscopic fundoplication. Patients with an Eckardt symptom score ≥4 were randomly assigned to pneumatic dilation (PD) using a 35 mm balloon or sham dilation. Primary outcome was treatment success, defined as an Eckardt score <4 and a minimal reduction of 2 points in the Eckardt score after 30 days. Secondary outcomes included change in stasis on timed barium oesophagogram, change in high-resolution manometry parameters and questionnaires on quality of life, reflux and dysphagia symptoms.

Results Forty-two patients were randomised. In the intention-to-treat analysis, the success rates of PD (7/21 patients (33%)) and sham dilation (8/21 patients (38%)) were similar after 30 days (risk difference −4.7% (95% CI (−33.7% to 24.2%) p=0.747). There was no significant difference in change of stasis on the timed barium oesophagogram after 2 min (PD vs sham: median 0.0 cm, p25–p75 range 0.0–4.3 cm vs median 0.0 cm, p25–p75 range 0.0–0.0; p=0.122) or change in lower oesophageal sphincter relaxation pressure (PD vs sham: 10.54±6.25 vs 14.60±6.17 mm Hg; p=0.052). Quality of life, reflux and dysphagia symptoms were not significantly different between the two groups.

Conclusion Pneumatic dilation with a 35 mm balloon is not superior to sham dilation for the treatment of persistent dysphagia after fundoplication.

Significance of this study

What is already known on this subject?

- Persistent dysphagia after laparoscopic fundoplication is a troublesome symptom, which can seriously affect quality of life and may even compromise adequate food intake.
- There is no evidence-based treatment for persistent dysphagia after laparoscopic fundoplication.

What are the new findings?

- Pneumatic dilation is not more effective than sham dilation in patients with persistent dysphagia after laparoscopic fundoplication.

How might it impact on clinical practice in the foreseeable future?

- There is no rationale to perform pneumatic dilation in these patients without any objective metric of obstruction or anatomical defect.

INTRODUCTION

Laparoscopic fundoplication is the most effective treatment for patients with GORD in whom acid suppressive medication does not provide sufficient relief.[1] During this operation, the fundus of the stomach is totally (Nissen fundoplication) or partially (Toupet fundoplication) wrapped around the distal part of the oesophagus. Postoperative dysphagia is a common side effect in most patients due to the postsurgical inflammation and oedema of the operated tissue. It usually resolves spontaneously within a couple of weeks.[2] However, in 3%–25.6% of patients, persistent dysphagia develops, defined as lasting more than 3 months postoperatively, which can seriously affect quality of life and may even compromise adequate food.[2–4] The management of persistent dysphagia after fundoplication is challenging. To exclude an anatomical defect, such as a slipped, malpositioned or herniated fundoplication, a radiograph or CT scan, and/or endoscopy are the preferred diagnostic instruments. In case of an anatomical defect, a reoperation should be considered. When no anatomical defect is seen, it is often thought that the antireflux wrap is 'too tight'.

Pneumatic dilation of the oesophagogastric junction (OGJ) including the antireflux wrap has been suggested to relieve dysphagia symptoms. Retrospective data suggest that pneumatic dilation has a positive effect in 50%–64% of patients with persistent dysphagia after laparoscopic fundoplication.[5–7] Evidence-based treatment for persistent dysphagia after antireflux surgery is lacking. While risks seem to be present, a prospective randomised controlled trial (RCT) with adequate blinding of patients was not conducted.[5–8] The aim of this study

was to evaluate the effect of pneumatic dilation on persistent dysphagia after fundoplication in a multicentre, single-blind, randomised sham-controlled trial.

MATERIAL AND METHODS

Study design

We performed a multicentre, single-blind, randomised sham-controlled trial in patients with persistent dysphagia (>3 months) after laparoscopic fundoplication at four medical centres between December 2015 and February 2020. Patients were randomly assigned to pneumatic dilation using a 35 mm balloon or sham dilation under deep sedation in order to provide an adequate control group. The study was conducted according to the principles of the Declaration of Helsinki, complied with Good Clinical Practice and the Medical Research Involving Human Subjects Act (WMO). The trial was prospectively registered at the Dutch National Trial Register under number NL5115. Written informed consent was obtained from all patients. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this clinical trial.

Patient selection

We included 42 adult patients with persistent dysphagia after laparoscopic fundoplication, defined as dysphagia lasting more than 3 months postoperatively. We included patients with continuous or intermittent dysphagia for solids and/or liquids. Patients were excluded if they had dysphagia before surgery, if they had undergone previous oesophageal dilations, had a history of (pseudo)achalasia or had an anatomical defect causing the dysphagia (slipped, malpositioned or herniated fundoplication, or a para-oesophageal herniation).

Study protocol and randomisation

If not previously performed, a high-resolution manometry (HRM), a timed barium oesophagogram and upper endoscopy were done to exclude an anatomical defect or achalasia as cause of the dysphagia. Patients were randomly assigned in a single-blind fashion to either pneumatic dilation or sham dilation in a 1:1 ratio (random block, maximum block size 6, no stratification) using a validated computer-generated randomisation program (ALEA, https://www.aleaclinical.eu). Patients were blinded for the treatment allocation. After 30 days, at the end of the study, patients were de-blinded for the treatment allocation. Emergency de-blinding was only possible by the principal investigator of this study who was also the endoscopist and by the research nurse who was not in contact with the patient.

Study procedures

Oesophageal HRM

Stationary oesophageal HRM was performed before and 30 days after treatment. A solid-state HRM catheter with 36 pressure sensors at 1 cm intervals (ManoScan ESO Catheter, Given Imaging, Los Angeles, California, USA) was placed transnasally. After correct positioning of the catheter and a period of accommodation, the patients swallowed 10 boluses of 5 mL of water in supine position according to standardised protocol.[9] Dedicated software (Manoview, Given Imaging, Los Angeles, California, USA) was used to analyse the recorded signals.

Timed barium oesophagogram

A timed barium oesophagogram was performed before and 1 month after treatment. After drinking 250 mL of barium-containing suspension, upright, frontal radiographs of the oesophagus were obtained at 1, 2 and 5 min. The height of the barium column above the OGJ and the maximum diameter of the distal oesophagus were measured in centimetres. The height of the barium column after 1, 2 and 5 min was used as a measure of oesophageal emptying.[10]

Pneumatic dilation and sham dilation

Patients fasted for a minimum of 8 hours prior to the endoscopy. All endoscopic procedures were performed under deep sedation using propofol. In order to ensure blinding, endoscopy nurses and anaesthesiology physician assistant were only made aware of the treatment arm after the patients were fully sedated. Nurses on the recovery were not informed of the treatment allocation and so they could not unintentionally disclose this. Oesophagus, stomach and duodenum were carefully inspected. If the patient was randomised for the pneumodilation, a guidewire was placed into the stomach and a non-inflated polyethylene balloon (Rigiflex balloon 35 mm, Boston Scientific, Massachusetts, USA) was introduced over the guidewire and positioned radiographically at the OGJ. The balloon was then fully inflated to 35 mm for 1 min at 5 PSI and another minute at 8 PSI. In case of a sham dilation, only a routine upper endoscopy under deep sedation with inspection was performed and the endoscope remained in the stomach for 5 additional min to keep the procedure duration similar. Patients who underwent a sham dilation were offered a pneumatic dilation after completion of the study.

Outcome measures

Primary outcome was treatment success, defined as an Eckardt score <4 and a minimal reduction of 2 points in the Eckardt score after 30 days. The total score ranges from 0 to 12 points, scoring the symptoms dysphagia, regurgitation and chest pain (0=absent, 1=occasional, 2=daily, 3=each meal) and weight loss (0=no weight loss, 1=<5 kg, 2=5–10 kg, 3=>10 kg).[11] Patients were excluded if they had an Eckardt score <4 at baseline. Secondary outcomes included change in stasis on timed barium oesophagogram, change in HRM parameters and change in symptoms and quality of life, measured by the Reflux Disease Questionnaire (RDQ), Brief Esophageal Dysphagia Questionnaire and Short Form Health Survey (see online supplemental material). Questionnaires were completed at baseline, 7 days after treatment (with exception of the RDQ) and 30 days after treatment. Patients completed the questionnaires independently and prior to the final meeting with the investigator, and these were collected before the allocation arm was disclosed to them.

Statistical analysis

Sample size calculation

Sample size calculation was based on three previously performed studies in which pneumatic dilation was found to have a positive effect in 50%–64% of patients with persistent dysphagia after fundoplication.[5–7] In these retrospective studies, no symptom questionnaires were used to assess treatment success. Treatment success was either retrospectively considered satisfactory when no further treatment was required[6] or defined as complete, partial or failure success by patients and physician evaluation.[5] In our study, we have used the Eckardt score as primary outcome measure. We anticipated that, based on the limited available retrospective data, 60% of the patients in the pneumatic dilation group would have an Eckardt score <4 and a minimal reduction of 2 points in the Eckardt score after 30 days.

The lowest documented effect of dilation in patients with persistent dysphagia is 17% in patients who underwent a

Savary-Gilliard dilation.[12] There are no published data about the natural course of persistent dysphagia after fundoplication, but given the small diameter of Savary-Gilliard bougies, it is unlikely that these have an effect and therefore we regarded 17% as the sham or placebo effect size. The estimated effect size of pneumatic dilation was set on 60%. The sample size required to achieve 80% power, with a predefined significance level of 0.05, was estimated at 19 per group. Considering a maximum dropout of 10%, 42 patients needed to be randomised.

Endpoint analysis

The primary endpoint, treatment success, was analysed according to the intention-to treat-analysis. In addition, the per-protocol analysis is reported. The intention-to-treat analysis included all patients who were randomised, the per-protocol analysis only considered patients who underwent either the pneumatic dilation or the sham dilation. The primary endpoint, rate of treatment success, was compared by using Pearson's X^2 test. For the secondary outcomes, the per-protocol population was used and adjusted for missing data. Normally distributed data were compared using unpaired t-test; non-normal distributed data were compared using the Mann-Whitney U test. All p values are two-tailed with the alpha level set at 0.05. Calculations were performed using IBM SPSS Statistics for Windows V.26.

Safety and data management

A Data and Safety Monitoring Board was appointed, consisting of a gastroenterologist, a paediatrician specialised in gastroenterology and an epidemiologist who were not involved in the trial. The Clinical Research Unit from the Amsterdam UMC monitored the study. All study data were collected using paper case report forms and later imported into the electronic data management system Castor EDC.[13] All authors had access to the study data and reviewed and approved the final manuscript.

RESULTS

Patient characteristics

In total 42 patients (13 men) were randomised and analysed according to the intention-to-treat approach. Three patients were excluded following randomisation, and did not receive the allocated treatment, (one patient had a large diaphragmatic hernia not detected previously and two patients withdrew consent before treatment was scheduled). Twenty patients underwent a pneumatic dilation and 19 patients underwent a sham dilation. One patient, who was randomised for sham dilation, terminated the study prematurely due to severe complaints and revoked consent. No follow-up data were obtained. Another patient, who was randomised for pneumatic dilation, had dysphagia complaints; however, he had a baseline Eckardt score of 1 and should not have been included. Both patients were regarded as treatment failure but were included according the per-protocol analysis (n=39). A participant flow diagram is shown in figure 1. Baseline demographic and clinical characteristics are shown in table 1.

Primary outcome

In the intention-to-treat analysis, pneumatic dilation and sham dilation generated equal success rates (7/21 patients (33%) in the PD group vs 8/21 patients (38%) in the sham group; risk difference −4.7%, 95% CI (−33.7% to 24.2%) p=0.747). Similar success rates were found in the per-protocol analysis (7/20 patients (35%) in the PD group vs 8/19 patients (42%) in the sham group; risk difference −7.1% (95% CI (−37.6% to 23.3%) p=0.648) (figure 2).

Secondary outcomes

There was no significant difference in reported symptoms and quality of life after 7 days (online supplemental table 1) and 30 days between the two groups (table 2). Furthermore, there was no significant difference in the Integrated Relaxation Pressure (IRP-4) after 30 days (PD: 10.54±6.25 mm Hg vs sham

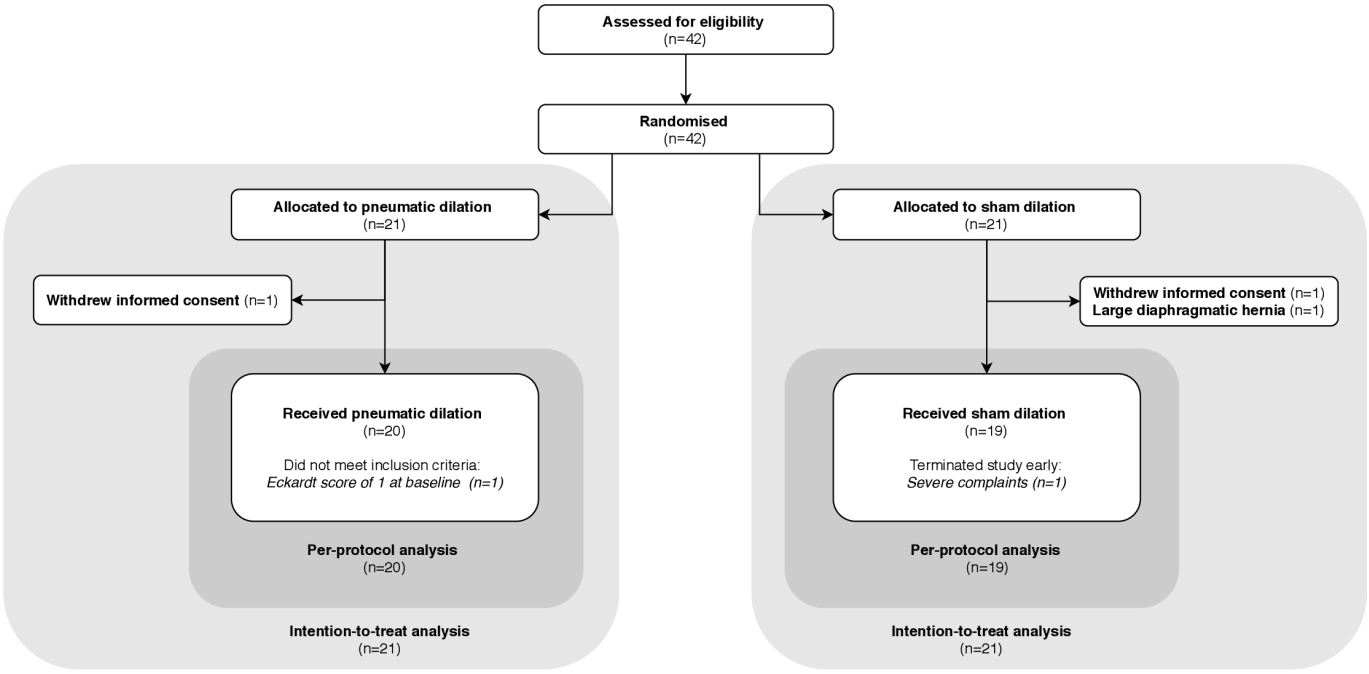

Figure 1 Participant flow diagram.

Table 1 Patient baseline characteristics (per-protocol population, n=39)

	Pneumatic dilation (n=20)	Sham dilation (n=19)
Age (mean±SD) (years)	53.65±15.58	56.16±12.37
Sex, n (%)		
Male	7 (35)	6 (31.6)
Female	13 (65)	13 (68.4)
BMI (mean±SD) (kg/m^2)	24.10±3.24	25.26±4.27
Eckardt score, median (p25–p75)	7.00 (4.25–8.75)	6.00 (5.00–9.00)
Type of fundoplication (n)		
Nissen	12	11
Toupet	6	7
Belsey	0	1
Thal	1	0
Unknown	1	0
Dysphagia, n (%)*		
Solid foods	20 (100)	19 (100)
Soft foods	9 (45.0)	9 (47.4)
Liquids	10 (50.0)	5 (26.3)
IRP-4 (mean±SD), (mm Hg)	11.22±6.94	13.59±8.10
Chicago classification (n)		
Normal	10	5
IOM	5	6
Absent contractility	1	3
OGJ outflow obstruction	3	5
Not performed	1	0
Timed barium oesophagram, median (p25–p75) (cm)		
Stasis after 1 min	0.0 (0.0–5.3)	0.0 (0.0–1.5)
Stasis after 2 min	0.0 (0.0–1.0)	0.0 (0.0–0.0)
Stasis after 5 min	0.0 0.(0–0.0)	0.0 (0.0–0.0)
BEDQ, median (p25–p75)		
Total score	22.00 (14.00–32.00)	20.00 (13.00–27.00)
Symptom severity	9.00 (5.00–12.00)	8.00 (5.00–11.00)
Symptom frequency	13.00 (10.00–20.00)	13.00 (8.00–18.00)
RDQ, median (p25–p75)		
Heartburn	1.75 (0.88–4.06)	3.00 (1.25–3.50)
Regurgitation	0.50 (0.00–2.25)	2.25 (0.50–2.75)
GORD	1.19 (0.88–3.07)	2.63 (1.13–3.13)
Dyspepsia	2.38 (1.13–4.13)	2.75 (0.75–4.00)
SF-36 (mean±SD)		
Physical health	33.19±8.25	36.19±8.71
Mental health	42.63±12.97	40.95±12.08

*Dysphagia for more than three times a week. Data derived from the BEDQ questionnaire.
BEDQ, Brief Esophageal Dysphagia Questionnaire; BMI, body mass index; IOM, ineffective oesophageal motility; IRP, Integrated Relaxation Pressure; OGJ, oesophagogastric junction; RDQ, Reflux Disease Questionnaire; SF-36, Short Form Health Survey.

14.6±6.17 mm Hg, p=0.052). HRM diagnoses were comparable with baseline (normal oesophageal motility (PD: 9 vs sham: 5), ineffective oesophageal motility (PD: 6 vs sham: 6), absent contractility (PD: 2 vs sham: 2), OGJ outflow obstruction (PD: 1 vs sham: 5) and one hypercontractile oesophagus in the PD group (table 2). Stasis on the timed barium oesophagogram after 1 min was significantly higher in the PD group (table 2), however this was not observed after 2 or 5 min. No adverse events occurred during the duration of this study in both groups.

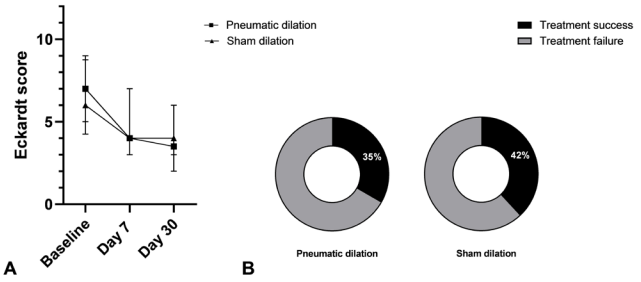

Figure 2 Results after 30 days. Per-protocol population. (A) Eckardt score at baseline, day 7 and day 30. Displayed as median and p25-p75. (B) Treatment success is defined as an Eckardt score < 4 and a minimal reduction of 2 points in the Eckardt score after 30 days (P= 0.648).

DISCUSSION

Laparoscopic fundoplication is a highly effective treatment for proton pump inhibitor-refractory gastro-oesophageal reflux disease. By restoring the integrity of the antireflux barrier, it heals reflux oesophagitis in 80.0%–88.4% and effectively reduces reflux symptoms in approximately 90% of the patients.[14–17]

Table 2 Results after 30 days

	Pneumatic dilation	Sham dilation	P value
Treatment success, n (%)			
Intention-to-treat (n=42)	7/21 (33)	8/21 (38)	0.747
Per-protocol (n=39)	7/20 (35)	8/19 (42)	0.648
Eckardt score, median (p25–p75)	(n=20) 3.50 (3.00–6.00)	(n=19) 4.00 (2.00–6.00)	0.876
IRP-4 (mean±SD), (mm Hg)	(n=19) 10.54±6.25	(n=18) 14.6±6.17	0.052
Chicago classification (n)			
Normal	9	5	
IOM	6	6	
Absent contractility	2	2	
OGJ outflow obstruction	1	5	
Hypercontractile	1	0	
Not performed	1	1	
Timed barium oesophagram, median (p25–p75) (cm)	(N=18)	(N=19)	
Stasis after 1 min	0.0 (0.0–6.7)	0.0 (0.0–0.3)	0.041
Stasis after 2 min	0.0 (0.0–4.3)	0.0 (0.0–0.0)	0.122
Stasis after 5 min	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.477
BEDQ, median (p25–p75)	(n=20)	(n=19)	
Total score	18.00 (10.00–31.00)	12.00 (9.00–29.00)	0.545
Symptom severity	8.00 (4.00–11.00)	7.00 (3.00–12.00)	0.944
Symptom frequency	11.00 (6.00–20.00)	7.00 (3.00–20.00)	0.398
RDQ, median (p25–p75)	(n=19)	(n=19)	
Heartburn	2.50 (1.00–4.00)	2.00 (1.00–3.50)	0.703
Regurgitation	0.25 (0.00–3.25)	0.00 (0.00–2.25)	0.606
GORD	1.25 (0.75–3.25)	1.25 (0.75–2.50)	0.599
Dyspepsia	2.25 (0.00–4.50)	2.00 (0.75–3.75)	0.691
SF-36 (mean±SD)	(n=19)	(n=17)	
Physical health	33.30±10.97	37.41±8.95	0.23
Mental health	41.73±11.71	41.29±11.78	0.911

BEDQ, Brief Esophageal Dysphagia Questionnaire; IOM, ineffective oesophageal motility; IRP, Integrated Relaxation Pressure; OGJ, oesophagogastric junction; RDQ, Reflux Disease Questionnaire; SF-36, Short Form Health Survey.

However, the increased barrier at the OGJ is associated with complications such as gas-bloat when patients lose the ability to belch and vent gastric air, the inability to vomit and of most troublesome, severe persistent dysphagia that may even compromise adequate food intake. Pneumatic dilation is widely regarded as useful treatment for persistent dysphagia after fundoplication and retrospective uncontrolled series report reasonably good efficacy rates, however this was never assessed in a controlled manner. Given the lack of good evidence, this treatment has never been part of routine clinical care in our country. We felt that a well-performed trial could either convince physicians in our country to perform this treatment in case of positive results or stop using it in places where it has been become part of routine clinical care. This is the first prospective, randomised, sham-controlled clinical trial investigating the effect of pneumatic dilation for persistent dysphagia after laparoscopic fundoplication. The results clearly demonstrate that pneumatic dilation is not more effective than sham dilation.

Although it seems that pneumatic dilations are safe in patients with persistent dysphagia after fundoplication, the demonstrated lack of efficacy in this study suggests that one should be hesitant to offer this treatment to patients. In the per-protocol analysis, 42% of the sham dilation patients achieved the primary outcome (compared with 35% in the pneumatic dilation group). In addition, a considerable proportion of patients reported sufficient relief of the dysphagia complaints after the sham dilation. The combination of a 'high' effect in the sham dilation group, the absence of stasis on the timed barium oesophagogram in nearly all patients and the absence of an abnormally high IRP in many subjects suggests that it is conceivable that the nature of the persistent dysphagia after fundoplication is often functional rather than obstructive. Furthermore, it is known that more invasive 'sham treatments' generally have larger placebo effects in clinical trials.[18] Unfortunately, there are no published data regarding the natural course of persistent untreated dysphagia after fundoplication. It is tempting to speculate that enhanced visceral perception plays a role in the genesis of the complaints and perhaps treatment that modulates this perception may benefit the patient more than a dilation. In a systematic review and meta-analysis, antidepressants have been shown to modulate oesophageal sensation and reduce functional chest pain.[19] However, the authors did not identify any RCTs describing the use of antidepressants in the context of functional dysphagia. Oesophageal-directed hypnotherapy might also benefit these patients, but the published literature on this topic is limited.[20]

With the goal of effectively reducing GORD and reducing the occurrence of dysphagia after surgery, patient selection has become stricter and new approaches have been developed to minimise the surgical complications. For example, patients with preoperative dysphagia and delayed oesophageal transit on barium contrast study are more likely to develop persistent dysphagia.[21 22] Therefore, many experts advocate a preoperative manometry to exclude major motility disorders (such as achalasia) or to modify the type of fundoplication.[23] Indeed, meta-analyses conclude that a partial fundoplication (Toupet, 270° posterior) is associated with a significantly lower risk of developing postoperative dysphagia compared with a total fundoplication (Nissen, 360°), with similar reflux control. In addition, the need for postoperative dilation for dysphagia is lower in patients who underwent a Toupet fundoplication.[16 24 25] We included patients after both Toupet and Nissen fundoplication. One could imagine that primarily patients that underwent Nissen fundoplication would benefit from pneumatic dilation. Although our study was not powered to detect a difference in this subgroup, we found similar rates of treatment success in both groups (online supplemental table 2).

In our study, we observed a slightly elevated IRP-4 at baseline in both groups compared with healthy individuals, but this is considered physiological after fundoplication and is also seen in patients that underwent antireflux surgery who do not have dysphagia.[26] After pneumatic dilation, we observed a trend towards a lower IRP-4; however, this did not reach a statistically significant difference. This may suggest that the pneumatic dilation has some effect on the lower oesophageal sphincter relaxation relaxation and/or antireflux wrap. Stasis on the timed barium oesophagogram was observed in only a small proportion of patients. Unexpectedly, stasis measured after 1 min was significantly higher in the pneumatic dilation group after 30 days (table 2), however this was not observed after 2 or 5 min. Given the small difference in stasis after 1 min and the notion that this can occur in healthy subjects, we do not regard this finding as clinically significant.[27] More importantly, we observed no difference between pneumatic dilation and sham dilation on quality of life, dysphagia and/or reflux symptoms.

There are several limitations to this study. At baseline, 8 of the 38 patients had some stasis on the timed barium oesophagogram after 2 min (range 1.5–11.7 cm). The lack of objective metric of obstruction in this studied population may have led to a selection bias in inclusion of patients with functional dysphagia. However, our experience is that the majority of patients, who present with this challenging clinical symptom after fundoplication, do not have any abnormalities on additional investigations. Including only patients with objective metric of obstruction (eg, stasis on the timed barium oesophagogram or elevated IRP-4) would have made this randomised clinical trial unfeasible. Although this study is underpowered for this specific subgroup, only three of eight patients with stasis at baseline after 2 min were defined as treatment success (two sham and one pneumatic dilation). At baseline, we observed several patients with OGJ outflow obstruction and ineffective oesophageal motility, which can be expected in patients who underwent antireflux surgery (table 1).[26 28] However, we also included four patients with an absent contractility after surgery. Interestingly, two out of four patients with absent contractility at baseline were defined as treatment success (1 sham and one pneumatic dilation).

Furthermore, we did not obtain information in all patients regarding their body weight after 30 days; therefore, this is not reported in the data. The follow-up and duration of blinding the patients was set at 30 days; which is relatively short. However, the effect of dilation was estimated to set in within a couple of days and we considered it unethical to keep patients blinded for a period longer than 30 days. Given the very small difference between pneumatic dilation (35% treatment success) and sham dilation (42% treatment success), it is extremely unlikely that a larger sample size would have resulted in a significant difference of pneumatic over sham. Although there are some limitations, we believe that this randomised single-blind, sham-controlled study has proven the lack of efficacy of pneumatic dilation for this group of patients without an objective metric of obstruction or anatomical defect.

CONCLUSION

In patients with persistent dysphagia after laparoscopic fundoplication, pneumatic dilation is not more effective than sham

dilation. Thus, there is no rationale to perform pneumatic dilation in patients without any objective metric of obstruction or anatomical defect. Other treatment options, such as modulation of oesophageal sensitivity, should be explored.

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Patient consent for publication Not required.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplemental information.

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Supplementary material

Questionnaires

The Reflux Disease Questionnaire (RDQ) is a 12-item questionnaire to obtain information on the current severity and frequency of reflux symptoms (heartburn, regurgitation and dyspepsia) and use of medication.[1] The RDQ uses a six-graded Likert scale, where 0 represents the most positive option and 5 the most negative one on frequency and intensity of the symptoms. The GORD, dyspepsia, heartburn and regurgitation sub dimension scores were calculated as the means of all frequency and intensity scores for the respective sub dimension.

The Short Form-36 Health Survey (SF-36) is a questionnaire on health- related quality of life. The SF-36 is composed of 36 questions and standardized response choices, organized into eight multi-item scales: physical functioning (PF), role limitations due to physical health problems (RP), bodily pain (BP), general health perceptions (GH), vitality (VT), social functioning (SF), role limitations due to emotional problems (RE), and general mental health (MH). The physical component summary (PCS) and a mental component summary (MCS) were calculated using normative data from the 1999 Dutch population.[2]

The Brief Esophageal Dysphagia Questionnaire (BEDQ) provides detailed information on the frequency, severity and duration of dysphagia. It consist of 10 questions to assess dysphagia, with a total score range of 0–40 (a high score is associated with high frequency, severity and duration). The Symptom Frequency scores subscale ranges from 0 to 25, The Symptom Severity scores subscale ranges from 0 to 15.[3-5]

Supplementary table 1. Results after 7 days

	Pneumatic dilation	Sham dilation	p-value
Eckardt score [median, p25-p75]	(n=19) 4.00, 3.00-7.00	(n = 18) 4.00, 3.00-7.00	0.817
BEDQ [median, p25-p75]	(n=18)	(n=18)	
Total score	21.50, 15.75-29.00	14.50, 10.75-27.25	0.205
Symptom severity	10.00, 5.75-11.25	6.00, 4.00-12.00	0.171
Symptom frequency	13.50, 6.50-17.50	8.00, 6.50-16.75	0.428
SF-36 [mean, SD]	(n=19)	(n=18)	
Physical health	32.20 ± 8.97	36.49 ± 9.62	0.169
Mental health	43.19 ± 11.40	39.72 ± 10.79	0.348

BEDQ, Brief Esophageal Dysphagia Questionnaire, SF-36, Short Form Health Survey; SD, Standard Deviation

Supplementary table 2. Type of fundoplication and treatment success

Treatment success	Pneumatic dilation	Sham dilation
Nissen	5 / 12 (42%)	4 / 11 (36%)
Toupet	2 / 6 (33%)	3 / 7 (43%)
Thal	0/1	-
Belsey	-	1/1
Unknown	0/1	-

Supplementary table 3. Eckardt score at baseline

		None	Occasional	Daily	Each Meal
Dysphagia	PD	10%	0%	10%	80%
	Sham	0%	10.5%	42.1%	47.4%
Regurgitation	PD	55%	35%	5%	5%
	Sham	36.6%	21.1%	21.1%	26.3%
Chest pain	PD	15%	40%	35%	10%
	Sham	10.5%	15.8%	36.8%	36.8%
		0 kg	**<5 kg**	**5-10 kg**	**>10 kg**
Weight loss	PD	45%	10%	25%	20%
	Sham	36.8%	15.%	21.1%	26.3%

Supplementary table 4. Eckardt score after 30 days

		None	Occasional	Daily	Each Meal
Dysphagia	PD	15%	35%	25%	25%
	Sham	15.8%	31.6%	21.1%	31.6%
Regurgitation	PD	55%	35%	5%	5%
	Sham	47.4%	36.8%	10.5%	5.3%
Chest pain	PD	15%	40%	35%	10%
	Sham	21.%	42.1%	36.8%	0%
		0 kg	**<5 kg**	**5-10 kg**	**>10 kg**
Weight loss	PD	60%	30%	0%	10%
	Sham	68.4%	15.8%	10.5%	5.3%

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