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**SHORT AND MEDIUM-TERM THERAPEUTIC EFFECTS  
OF PNEUMATIC DILATATION FOR ACHALASIA:  
A 15-YEAR TERTIARY CENTRE EXPERIENCE**

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## SHORT AND MEDIUM-TERM THERAPEUTIC EFFECTS OF PNEUMATIC DILATATION FOR ACHALASIA: A 15-YEAR TERTIARY CENTRE EXPERIENCE

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### Abstract

**Background:** Pneumatic dilatation (PD) is a commonly used endoscopic technique to weaken the lower oesophageal sphincter in patients with achalasia. It is considered as the most effective non-surgical therapeutic option for achalasia, but further data on the overall effectiveness and rate of complications is needed.

**Aims:** To determine the short- and medium-term therapeutic effectiveness of PD for achalasia and estimate the cumulative probability of remaining in remission over one year after a single treatment. The study also aimed to identify clinical predictors of therapeutic outcome achieved by PD and assess for PD-related complications.

**Methods:** A total of 26 patients with achalasia who were treated with PD between 1997 and 2011 at a tertiary care centre were followed for up to 1 year. Data related to demographics, clinical symptoms and PD-related complications were collected. Short (1 and 3 months) and medium (1 year) term therapeutic effectiveness of PD was assessed with the use of the Eckhart scoring system for evaluation of clinical symptoms. The probability of staying in remission one year after a single PD was determined by using a Kaplan-Meier estimator. In order to prevent major complications, limited maximal pressure of no more than 11 PSI was used during PD.

**Results:** Twenty-six patients with symptomatic achalasia (mean age  $47.1 \pm 18.5$  years, 82% males) underwent 44 PD procedures (mean 1.7/patient). Thirteen patients (50%) had a single PD, 10 patients (38%) had two dilatations, and 3 patients (12%) had three or more dilatations over one year. Nineteen out of the 26 patients (73%) were in remission at one and three months each, following the initial PD. Seventeen out of the 26 patients (65%) remained in remission after one year. A total of 5 patients (19%) were referred for surgery over 1 year due to lack of success of the endoscopic treatment. The mean Eckhart symptom scores, at 1 month ( $3.2 \pm 1.2$ ), 3 months ( $3.5 \pm 1.3$ ) and 1 year ( $1.8 \pm 0.6$ ) after the initial PD, were significantly lower when compared to the mean initial Eckhart symptom score ( $9.7 \pm 4.4$ ,  $P < 0.05$ ). Using a symptom score above 3 as a cutoff value for treatment failure, the probability of remaining in remission (relapse-free) after a single dilatation was 35% at one year. Patient gender appeared as an important treatment outcome predictor. Namely, 4 of the 5 patients (80%) with PD treatment failure were males. There were no major complications from the 44 PDs. One patient (3.8%) developed significant heartburn. The majority of PDs (33/44, 75%) were followed with minor, subclinical oesophageal mucosal bleeding from the dilation site as seen on post-dilatation oesophagoscopy.

**Conclusion:** Pneumatic dilatation is an effective short and medium term treatment option for the majority of patients with achalasia without significant related complications. Further studies are warranted to assess the possible role of limited maximal pressure use of no more than 11 PSI during PD in preventing oesophageal perforations.

**Key words:** achalasia, pneumatic dilation, short and medium-term therapeutic effects.



## Introduction

Achalasia is an oesophageal smooth muscle motility disorder in which the lower oesophageal sphincter (LES) fails to relax. Selective loss of inhibitory nitrergic neurons in the myenteric plexus, resulting in relatively unopposed excitation by the cholinergic system is considered to be the underlying mechanism of achalasia. Consequently, there is complete absence of effective oesophageal peristalsis. Although achalasia is a relatively uncommon disorder affecting on average 1 per 100,000 individuals, it can cause severe symptoms (dysphagia, regurgitation, retrosternal pain and weight loss) and result in significant long-term morbidity. [1] The etiology of this disorder remains largely unknown and there is no cure, as all available treatment options for achalasia are palliative. Therapy is focussed towards decreasing LES pressure to facilitate the emptying of oesophageal contents and relieve the functional obstruction at the distal oesophagus. There are several modalities to treat achalasia including: medications, endoscopic modalities [injection of botulinum toxin, PD or peroral endoscopic myotomy (POEM)] and surgery. Mechanical disruption of muscle fibres in LES can be accomplished with PD, POEM or surgical myotomy and biochemical reduction of LES pressure can be achieved with botulinum toxin. Peroral endoscopic myotomy was first introduced by Inoue H, et al., in 2008, and the first results were published in 2010. [2] But this sophisticated technique is still limited to a relatively small number of tertiary referral centres throughout the world. Due to the lack of comparative trials there are no generally accepted therapeutic practices. [3]

Pneumatic dilatation is considered to be the most effective non-surgical management option for patients with achalasia. Although considered less effective compared to surgery, recently there have been reports suggesting similar overall outcomes between PD and surgical myotomy in patients followed for up to 10 years. [4, 5] Complications risk (most commonly perforation) is approximately 3-5% in patients treated with PD, although there is wide variability in different reports (range - 0-21%). [6, 7] Successful PD may obviate the need for surgery. [3]

This is a retrospective report from a tertiary care, academic institution focussing on the short (1 and 3 months) and medium (1 year) term therapeutic effectiveness of PD in patients with achalasia. The study also aimed to identify clinical predictors of therapeutic outcome achieved by PD and the rate of complications. This data may add to the currently relatively limited available information on the durability of therapeutic effects achieved by PD in patients with achalasia.

## Methods

All patients diagnosed with achalasia and treated with PD (N = 31) at the University Gastroenterology and Hepatology Clinic in Skopje, Macedonia between 1997 and 2011 were identified. The diagnosis of achalasia was established by standard investigations such as radiographic studies as well as upper digestive endoscopy, and in some patients, oesophageal transit scintigraphic studies and trans-abdominal ultrasound were performed. All patients had undergone upper digestive endoscopy to exclude other causes of dysphagia, particularly malignancy. All patients with no contra-indication to sedation with diazepam or midazolam, age  $\geq 18$  years and  $\leq 80$  years and who were able to give written consent were included in this study. Patients were excluded from this analysis if they had undergone prior alternative primary therapy with either surgical myotomy or botulinum toxin injection, they had a diagnosis of pseudoachalasia, previous mediastinal surgery, any medical condition which in the judgment of the investigator makes the subject a poor candidate for the procedure, pregnant or lactating female or had insufficient data available to be certain of a diagnosis of achalasia. Previous medical therapy with nitrates and calcium channel blockers was not considered as an exclusion criterion.

Radiographic studies were performed on 24 patients prior to pneumatic dilatations. Multiple films of full column views were obtained in prone, prone-oblique and upright positions. All of the evaluated patients had typical radiologic findings such as dilated oesophageal body, non-propulsive tertiary contractions or "bird beak" appearance (Figure 1).



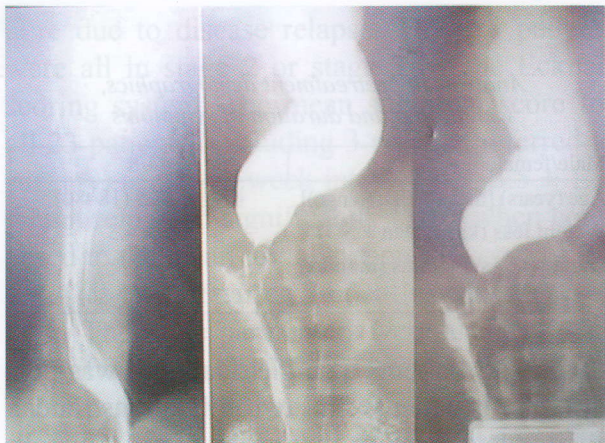


Figure 1 – From right to left – radiographic studies of oesophagus before and after dilation

All of the oesophageal dilatation procedures were performed by two physicians under fluoroscopic control. Diazepam or midazolam were used for sedation. A liquid diet was prescribed two days preceding the dilatation. All patients were advised to fast for at least 12 hours prior to the procedure and were restricted from oral intake post-procedure, on the day of intervention. A 3.5 cm Rigiflex balloon (Boston Scientific Corp, Rigiflex ABD, USA) was

used for the PD in all patients. Prior to procedure, the balloon had been inflated and checked for leaks or deformities. A guidewire was passed through the working channel of the endoscope into the stomach and the scope was then removed, taking care to maintain the position of the guidewire in the stomach. The balloon and tip of the catheter were lubricated and passed over the previously placed guidewire. After the dilator was passed into the proximal stomach, it was positioned fluoroscopically at the oesophago-gastric junction and inflated, until maximal pressure limited to 11 PSI, and then kept at that degree for 120 seconds (Figure 2). The patients were in a supine position and the upper part of their body was raised to 30°, to avoid aspiration during intervention. Immediately after the procedure, a second-look endoscopy was done to check for any appearance of bleeding or oesophageal mucosal tears. In addition, all patients were examined for post-interventional leak of contrast and early perforation using a routine post dilation oesophagography.

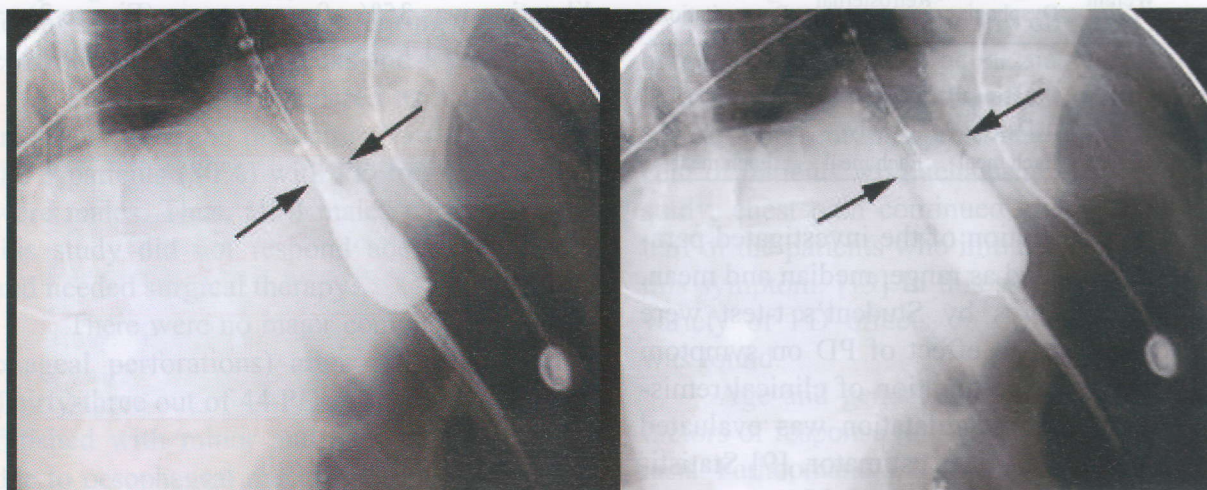


Figure 2 – Left: "Waist" of the balloon as it is being insufflated with air and pre-injected with a small amount of contrast, and right: obliteration of waist with balloon fully inflated

The patients were followed for the appearance of any complications including oesophageal perforation as the major one and bleeding, intramural haematomas, oesophageal mucosal tears and gastroesophageal reflux disease.

After the initial treatment with PD patients were regularly clinically followed up at 4 weeks, at 12 weeks, and at one year, or upon

recurrence of symptoms. At each of these encounters patients were asked about the presence of oesophageal symptoms such as dysphagia, regurgitation and a retrosternal pain sensation. If symptoms were present their frequency was assessed by a symptom score system developed by Eckhart et al. (Table 1). [8] Accordingly, a completely asymptomatic pati-



ent would have a symptom score of 0 and a most severely affected patient would have a score of 12. Based on these scores 4 clinical stages were identified: stage 0 (score 0–1); stage I (score 2–3); stage II (score 4–6) and stage III (score > 6). Patients in stages 0 or I were considered to be in clinical remission and those who reached stages II or III were considered to be treatment failures.

Patients were also asked about the amount of weight loss before the initial procedure and at each of the follow-up visits. This data was available for 26 (83.87%) of the 31 treated patients.

Patients with scores > 3 or those who wished to proceed with interventions were offered additional PDs. If a third dilatation failed to improve symptoms, surgery was indicated and patients were referred to a digestive surgeon.

Table 1

*Eckhart scoring system for evaluation of clinical symptoms*

Score	Symptoms			
	Weight loss	Dysphagia	Retrosternal pain	Regurgitation
0	None	None	None	None
1	< 5kg	Occasional	Occasional	Occasional
2	5–10kg	Daily	Daily	Daily
3	> 10kg	Each meal	Each meal	Each meal

The distribution of the investigated parameters is described as range, median and mean. Repeated measures by Student's t-test were used to analyse the effect of PD on symptom score decrease. The duration of clinical remission after pneumatic dilatation was evaluated using the Kaplan-Meier estimator. [9] Statistical significance was set at  $P < 0.05$ .

## Results

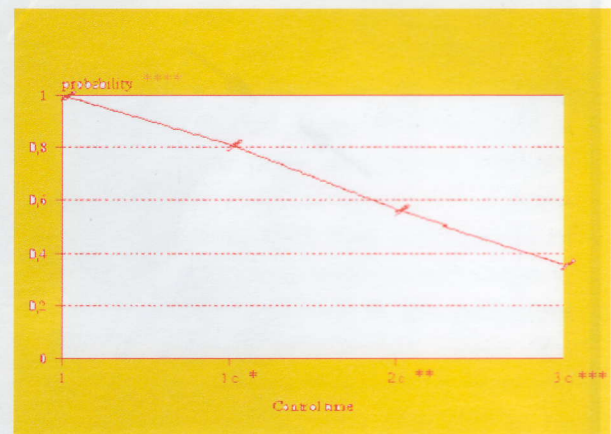
Of 31 consecutive patients diagnosed with achalasia and treated with PD between 1997 and 2011 at our Clinic, 26 (84%) were analysed in this study. The residual 5 patients were excluded due to lack of available data. All included patients were analysed for demographics, weight loss and symptoms length. (Table 2) Prior to first PD all 26 patients reported dysphagia, retrosternal pain and regurgitation on a daily basis.

Table 2

*Analysis of pretreatment demographics, weight loss and duration of symptoms*

Male/female	44/8
Age (years) [mean $\pm$ SD, (range)]	47.1 $\pm$ 18.5 (18–80)
Weight loss (kg) (mean $\pm$ SD)	8.7 $\pm$ 4.3
Duration of symptoms (months) [mean $\pm$ SD, (range)]	31 $\pm$ 10 (6–84)

In 13 patients a single dilatation was performed, 10 patients had two dilatations, and 3 patients had three or more dilatations. Overall, a total of 44 PDs were performed on the 26 patients (mean 1.7 PD per patient). At the first follow-up evaluation after 4 weeks, 15 patients (57.6%) had become completely asymptomatic, 4 patients (15.4%) were markedly improved (had score < 3), 4 patients (15.4%) were mildly improved (had score > 3) and 3 patients (11.6%) had no improvement at all. The mean symptom score had decreased from  $9.7 \pm 4.4$  to  $3.2 \pm 1.2$  at 4 weeks ( $P < 0.05$ , paired Student's t-test). Using a symptom score above 3 as a cutoff value for treatment failure, the probability of remaining in remission (relapse-free) after a single dilatation was 35% after one year. (Figure 3)



\* 1c – first control at 4 weeks

\*\* 2c – second control at 12 weeks

\*\*\* 3c – third control at 1 year

\*\*\*\* Probability of staying in remission

*Figure 3 – Cumulative proportion of patients (Kaplan-Meier analysis) remaining in remission (stage 0–1) one year after a first pneumatic dilatation*

At 12 weeks after the primary dilatation, 3 patients (11.6%) were referred to surgery due to lack of success of endoscopic treatment. At that time there were 6 patients (23%) who underwent a second endoscopic dilatation procedure.



due to disease relapse. These 6 patients were all in stage 2 or stage 3 by the Eckhart scoring system. The mean symptom score for all 23 patients (excluding 3 patients referred to surgery) at the 12 week interval was  $3.5 \pm 1.3$ , which remained significantly lower when compared to the mean initial symptoms score of  $9.7 \pm 4.4$  ( $P < 0.05$ , paired Student's t-test).

The same parameters were analyzed at 1 year after the initial PD. There were an additional 2 patients who were treated surgically, increasing the total number of individuals referred for surgery to 5 (19.2%). There were 7 patients who required an additional 12 dilatations in total for symptom relief. The mean symptom score for the 21 treated patients with PD (excluding 5 surgically treated patients) at one year interval was  $1.8 \pm 0.6$ . This score was significantly lower than the mean initial score ( $9.7 \pm 4.4$ ,  $p < 0.05$ ). 17 of the 21 patients (81%) evaluated at a one year period after initial PD were completely asymptomatic or markedly improved (score  $< 3$ ). There were 4 patients with a mild improvement (score  $> 3$ ). No statistically significant variety of PD effects on different symptoms was found during each of the control points at 4, 12 weeks and 1 year.

Patient gender appeared as an important treatment outcome predictor. Namely, 4 out of the 5 patients (80%) with PD treatment failure were males. Thus, all 4 males participating in this study did not respond adequately to PD and needed surgical therapy.

There were no major complications (oesophageal perforations) after PD in our study. Thirty-three out of 44 PDs (75%) in 26 patients finished with minor and self-limited bleeding due to oesophageal mucosal tears, confirmed by second-look endoscopy made after the procedure. No case of haematemesis was detected. Appearance of gastroesophageal reflux disease symptoms was registered in only 1 (3.8%) patient.

### Discussion

It is estimated that 71–90 % of patients with achalasia respond initially to PD, but many patients subsequently relapse. [10–12] Although retrospective analyses of PD in patients with achalasia show good to excellent sustained res-

ponses in two-thirds of patients, prospective studies suggest a less favourable prognosis, with more than 50 percent of patients relapsing over a five-year period. [13] The results of this study are consistent with such prior reports, relating to the findings of good short and medium term responses, with 73% (17/23) and 81% (17/21) of patients being totally asymptomatic or markedly improved at three months and one year after treatment, respectively. In a randomized controlled trial J. Mikaeli determined a cumulative 12-month remission rate of 53%, after a single pneumatic dilatation. [14] In addition, reviews found that PD, as the most commonly used nonsurgical means of treating patients with achalasia, results in symptom improvement in up to 90% of patients. [15]

Relapse-free survival data from different studies show different results. According to the results from retrospective studies, the cumulative proportion of patients remaining in remission one year after multiple PDs remains within 57–80%. [16, 17] In this study, the probability of staying in remission (relapse free) after a single PD was 35%.

PD may not be equally effective for relieving all symptoms of achalasia. In one report, for example, PD had little effect on chest pain, which is present in approximately 40 to 60 percent of patients with achalasia. [18] In another study, chest pain continued after PD in about half of the patients who initially complained of this symptom. [19] In this study no significant variety of PD effects on different symptoms was found.

Age and gender were implicated as predictors of response to PD in patients with achalasia. Farhoomand and colleagues, in their retrospective study of 49 men and 16 women, concluded that young men treated with a 3.0 cm balloon required repeat treatment more frequently than young women (hazard ratio 1.65). [20] Results from other retrospective studies endorsed male gender, age at presentation under 50 years, pulmonary symptoms, absence of chest pain, and failure to achieve a reduction in LES pressure  $> 50\%$  as predictors of poor outcome. [17, 20] In this study male gender also appeared as a strong indicator of unsuccessful outcome by PD as all 4 male patients failed PD and



needed surgical treatment. Furthermore, these 4 individuals represented 80% (4 out of 5) of all patients referred for surgery. However, given the limited number of males included in this study, it is difficult to draw strong conclusions on the predictive role of gender to PD effectiveness.

Among complications of PD, oesophageal perforation is the major one and occurs in approximately 3 to 5 percent of patients in most series, although the range varies from 0 to 21 percent. [6, 7, 11] In this trial no significant complications (oesophageal perforations) were observed. It seems to be a result of the use of limited maximal pressure of no more than 11 PSI during PD. Namely, Nair LA et al., in their retrospective cohort study using multivariate analysis, determined the use of inflation pressure > 11 PSI as an independent risk factor for developing complications. [21] Interestingly, in this trial there was a high percentage (75%) of post-interventional but minor and self-limited bleedings due to oesophageal mucosal tears, without clinical significance. Absence of major bleeding is consistent with the results from other studies, but the presence of a high percentage of oesophageal mucosal tears manifested with self-limited bleeding, differs a lot [7, 21]. It might be supposed that these were only morphological findings during a second-look endoscopy and should not be accepted as a complication of the procedure.

### Conclusion

In conclusion, pneumatic dilatation is an effective short- and medium-term treatment option for achalasia in a substantial number of patients. In this report, the PD success rate at a one year interval reached above 80%.

Male gender is predictive of treatment failure with PD.

Pneumatic dilatation is a safe treatment option for achalasia without significant complications. According to the high rate of occurrence without clinically important consequences, minor bleeding due to oesophageal mucosal tears should not be treated as a complication of the procedure.

Further studies are warranted to assess the possible role of limited maximal pressure use of no more than 11 PSI during PD in preventing oesophageal perforations.

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## Резиме

### ТЕРАПЕВТСКИ ЕФЕКТИ НА КРАТОК И СРЕДЕН РОК ОД ПНЕВМАТСКА ДИЛАТАЦИЈА КАЈ АХАЛАЗИЈА: 15 ГОДИНИ ИСКУСТВО ОД ТЕРЦИЕРЕН ЦЕНТАР

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**Вовед:** Пневматската дилатација (ПД) е често применувана ендоскопска техника за намалување на тонусот на долниот езофагеален сфинктер кај пациенти со ахалазија. ПД се смета за најефикасна нехируршка терапевска опција за пациентите со ахалазија, но за проценка на севкупната ефикасност и стапката на појава на компликации од истата, неопходни се дополнителни податоци.

**Цел:** Да се одредат краткорочните и долгорочните ефекти на ПД кај ахалазија и кумулативната веројатност за одржување на ремисија по една година од примената само на една сеанса на ПД. Студијата има за цел да ги утврди клиничките показатели кои ќе го предвидат терапевтскиот исход од ПД, како и стапката на појава на компликации.

**Методи:** Вкупно 26 пациенти со ахалазија третирали со ПД во период од 1997 до 2011 година во нашата терциерна здравствена установа беа следени во тек на една година. При тоа беа следени демографските податоци, клиничките симптоми и појавата на компликации како резултат на ПД. Со примена на Eckhart-овиот систем за скорирање, наменет за евалуација на клиничките симптоми, беше анализиран краткорочниот (1 и 3 месеци) и среднорочен (1 година) терапевтски ефект. Со примена на Kaplan-Meier-овиот тест беше одредувана веројатноста за одржување на ремисија, една година по примена само на една сеанса на ПД. Со цел да се спречи појава на тешки компликации, во текот на ПД, беше применуван ограничен максимален притисок не повеќе од 11 PSI.

**Резултати:** Дваесет и шест пациенти со симптоматска ахалазија (средна возраст  $47.1 \pm 18.5$  години, 82% мажи) беа третирали со 44 ПД (просечно 1,7/пациент). Тринаесет пациенти (50%) беа третирали со една сеанса на ПД, 10 пациенти (38%) со две дилатации и 3 пациенти (12%) со три или повеќе во текот на една година. Деветнаесет од вкупно 26 пациенти (73%), беа во ремисија, по еден и три месеци од почетната ПД. Седумнаесет од 26 пациенти (65%) останаа во ремисија по една година. Како резултат на неуспешен ендоскопски третман, вкупно 5 пациенти (19%) беа упатени на хируршко лекување по една година. Средните вредности на симптом скорот, по 1 месец ( $3,2 \pm 1,2$ ), 3 месеци ( $3,5 \pm 1,3$ ) и една година ( $1,8 \pm 0,6$ ) по почетната ПД беа значајно пониски споредено со средниот Eckhart-ов симптом скор ( $9,7 \pm 4,4$ ,  $P < 0,05$ ). Веројатноста да се остане во ремисија по една година, по примена само на една сеанса на ПД, изнесуваше 35%, применувајќи ја притоа вредноста 3 за симптом скорот како гранична за неуспешен третман. Полот на испитаниците се покажа како важен предиктор за терапевтскиот исход. Имено, 4 од 5 со неуспех од терапијата со ПД беа мажи. Не беа регистрирани тешки компликации во рамките на 44 ПД. Кај еден пациент (3,8%) беше регистрирана појава на значајни рефлуксни епизоди. Повеќето од ПД (33/44, 75%) резултираа со минорно и субклиничко мукозно езофагеално крвавење од местото на дилатација, што беше регистрирано со езофагоскопија направена по ПД.

**Заклучок:** Пневматската дилатација е ефикасна терапевска опција на краток и среден рок за повеќето пациенти со ахалазија и без тешки компликации. Со цел да се иследи можната



улога на примената на ограничен максимален притисок не повеќе од 11 PSI во тек на ПД, во обид за превенција на појавата на езофагеални перфорации, неопходни се дополнителни студии.

**Клучни зборови:** ахалазија, пневматска дилатација, краткорочни и среднорочни терапевтски ефекти.

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