

## Original article

# Mid term results of pneumatic balloon dilatation in patients with achalasia

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## SUMMARY

**AIM:** In this retrospective study we report the mid term results of a single center in patients with primary achalasia undergoing balloon dilatation. **METHODS:** Between April 1997 and May 2007, 82 patients with primary symptomatic achalasia (diagnosed by clinical presentation, manometry, esophagoscopy, and barium esophagogram) underwent endoscopic balloon dilatation. They were followed up clinically for 1 year after the last session. **RESULTS:** Symptoms were dysphagia ( $n = 82$ , 100%), regurgitation ( $n = 13$ , 16%), chest pain ( $n = 4$ , 8%), and weight loss ( $n = 36$ , 43%). A total of 98 dilations were performed; 68 patients (83%) underwent a single dilatation, 12 (15%) required a second procedure within a median of 1,7 mo (range 0.8- 2,0 mo), and only 2 patients, (2%) who were poor surgical candidates underwent a third procedure. Post-procedural seven of the 12 patients with no improvement after the second dilatation were considered for surgical myotomy and they were lost to follow up. Seven patients (5.4%) had esophageal pain and one patient had upper gastrointestinal bleeding. No perforations occurred. After one year 58 of the 75 remaining patients (78%) were in clinical remission, 10 (13%) presented the same symptomatology and only 7 patients (9%) deteriorated. **CONCLUSION:** Balloon dilatation is a safe and effective treatment for primary achalasia. The beneficial results remain after one year of follow up.

**Key words:** Pneumatic dilatation; Primary achalasia

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## INTRODUCTION

Achalasia is a rare primary motility disorder of the esophagus characterized by aperistalsis of the body of the esophagus, and incomplete Lower Esophageal Sphincter (LES) relaxation with swallowing. The pathogenesis of idiopathic achalasia remains unclear, although a viral cause, genetic influences (associations with HLA loci) and autoimmune processes have been postulated. Degeneration and significant loss of nerve fibers, associated with an inflammatory infiltration of the myenteric plexus in idiopathic achalasia, provide evidence of an immune-mediated destruction of the myenteric plexus, possibly through an apoptotic process.<sup>1,2,3</sup>

Treatment is strictly palliative. Current medical and surgical therapeutic options (pneumatic dilatation, surgical myotomy, and pharmacologic agents) aim to reduce the LES pressure and to facilitate esophageal emptying of retained food and liquids by gravity and hydrostatic pressure. Gastroenterologists prefer pneumatic dilatation as the first therapeutic step, due to its low cost and high success rates, ranging from 70% to 90%.<sup>4,5,6,7,8</sup> The aim of the present study was to evaluate the mid term results of endoscopic balloon dilatation treatment for achalasia, over an 1 year observation period.

## PATIENTS AND METHODS

Eighty-two consecutive patients (42 men, 40 women), with age range from 18 to 81 years, mean  $46 \pm 11$  years, who had undergone pneumatic dilatation for achalasia during a 10-year period (April 1997 and May 2007) were reviewed retrospectively. The diagnosis of achalasia was based on symptoms, barium swallow contrast studies, endoscopic and manometric findings. Exclusion criteria included pseudoacha-

lasia, prior endoscopic or surgical therapy and inadequate data. A clinical record was obtained especially for dysphagia, regurgitation, chest pain and weight loss. Esophageal manometry was performed in all patients after an overnight fast using a low compliance, pneumohydraulic, water infusion system (Synectics Medical USA) and an eight lumen, manometric catheter. The catheter had four ports radially oriented (90°) near the tip and four more centrally positioned, 5 cm apart (5, 10, 15, and 20 cm from the tip). The recording sites were connected to an eight-channel polygraph (Synetics Medical AB, Stockholm, Sweden). The manometric catheter assembly was passed transnasally without any sedation into the stomach. The LES pressure was determined using the station pull through technique and recorded as the mean of four measurements at mid-respiration. Completeness of LES relaxation (normal >85%) was assessed as percent decrease from resting LES pressure to gastric baseline, following wet swallows. Esophageal body motility was recorded at 3, 8, 13, and 18 cm above the LES in response to 5 mL swallows of water at 30-second intervals. The diagnostic criteria for primary achalasia were aperistalsis of the esophageal body and/or incomplete LES relaxation after exclusion of malignancy or peptic strictures by upper gastrointestinal endoscopy. Once the diagnosis was confirmed, the patients were offered pneumatic dilatation or Heller myotomy as treatment options and they signed informed consent. All patients chose balloon dilation as an initial therapeutic procedure and surgical intervention if the dilatations were unsuccessful. All dilatations were performed with a 30mm Rigidflex (Microvasive, Boston Scientific Corporation, Boston, MA, USA) achalasia balloon dilator by an experienced gastroenterologist. After a liquid diet for 48 h and an overnight fast, sedation for upper gastrointestinal endoscopy was administered using intravenous midazolam (2-5 mg), as required. Submucosal contrast injection was performed in order to mark the gastroesophageal junction. A stiff guidewire was placed into the stomach through the endoscope and the balloon dilator was passed over the guidewire and positioned at the esophagogastric junction under fluoroscopic control. While maintaining the balloon catheter into position by fixation against the bite guard, the balloon was fully inflated with air up to 9 psi. Full inflation was confirmed visually by the loss of the waist at the midpoint of the balloon and inflation was maintained for 1-3 min. A through the scope water-soluble contrast examination immediately after the dilatation to exclude perforation, was performed in all patients.

The result of treatment was classified as follows: (a)

Clinical remission (free of symptoms) b) no clinical response and (c) deterioration

All data are expressed as the mean±SD.

## RESULTS

Symptoms at presentation were dysphagia (n = 82, 100%), regurgitation (n = 13, 16%), chest pain (n = 4, 8%), and weight loss (n = 36, 43%). The mean duration of symptoms was 29.1±36.2 m. Vigorous achalasia was diagnosed by esophageal manometry in all four patients with chest pain. A total of 98 dilatations were performed; 68 patients (83%) underwent a single dilatation, 12 (15%) required a second procedure within a median of 1,7 mo (range 0.8-2,0 mo), and only 2 patients (2%) with severe cardiac failure who were poor surgical candidates underwent a third procedure. (Table) Seven patients (5.4%) experienced esophageal pain a few hours after dilatation and had a gastrograffin swallowing which was normal in all. One patient had a melena, followed by a fall of hematocrit from 44% to 36%. Endoscopy showed a single linear mucosal tear (Mallory-Weiss). Bleeding stopped spontaneously and the patient's course was uneventful. No patient had an emergency surgery.

Seven of the 12 patients had no clinical improvement after the second dilatation and were considered for surgical myotomy but they were lost to follow up. After one year, 58 of the 75 remaining patients (78%) were in clinical remission, 10 (13%) presented with the same symptomatology and 7 patients (9%) deteriorated. All 17 the patients of the last two groups were considered for Heller-myotomy.

## DISCUSSION

Pneumatic dilatation has been the first-line therapeutic

**Table** Demographic data, symptoms and number of procedures

Age (yr) [median (range)]	46 (18-81)
Gender (M/F)	42/40
Dysphagia	82 (100%)
Regurgitation	13 (16%)
Chest pain	4 (8%)
Weight loss	36 (43%)
Mean duration of symptoms (mo)	29.1±36.2
No of procedures	98
No of patients undergoing	
1 procedure	68
2 procedures	12
3 procedures	2

option for achalasia. The reported success rate varies widely, with figures ranging from 59%. The differences may be due to variable definitions of success, and to the techniques applied. The Rigiflex balloon dilator has been used in our department for the last 10 years, and data from the group of patients studied in this report compare favorably with data from previous studies, with an initial success rate of more than 80% in the 1<sup>st</sup> year. So far there is no standardized protocol for the size of the Rigiflex dilator.

The perforation rate with the Rigiflex balloon dilator ranges from 0% to 6.6%<sup>10</sup>, and gradual balloon dilatation starting with a 30-mm balloon dilator and progressing to 35 and 40 mm if necessary appears to be the safest approach.<sup>11</sup> In our study no perforation occurred as demonstrated by Gastrografin swallowing, performed following dilatation. The use of immediate contrast studies to exclude perforation has become routine and this approach is generally recommended. However it must be emphasized that an immediate contrast study may not always exclude a perforation, that may become clinically evident several hours later<sup>12</sup>. Less common complications, including intramural hematoma, diverticula of the gastric cardia, mucosal tears, reflux esophagitis, prolonged post-procedure chest pain, fever, hematemesis with or without changes in hematocrit, and angina, may occur after pneumatic dilatation<sup>5</sup>. In our series, a patient developed hematemesis due to a Mallory-Weiss lesion, which is an uncommon complication.

Finally, there is no consensus as to whether repeated pneumatic dilatations are associated with longer remission rates. A number of studies have shown that the additional sessions of pneumatic dilatation are followed by a longer duration of remission (10 years follow-up), while others believe that subsequent pneumatic dilatations after the second or third dilatation are less likely to result in a sustained remission, and surgical intervention should be considered for patients who have had two (or three) unsuccessful sessions of pneumatic dilatations.<sup>[12,13,14,15,16]</sup> To our experience, before recommending surgery a second procedure is required and can be successful in the majority of patients.

In conclusion, this study shows that pneumatic dilatation is a safe and effective treatment for achalasia. The beneficial results persist for at least one year.

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