

# The endoscopic pneumatic balloon dilation in treating achalasia in a Moroccan center

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## ABSTRACT

**Aim of the work:** Achalasia is a rare pathology whose physiopathogenesis is mysterious. The treatment is based on endoscopic pneumatic dilation (PD) and surgery. The aim of our work is to show our experiment about endoscopic pneumatic dilation as the principal treatment suggested for patients presenting achalasia. **Material and Method:** It is a retrospective study relating 21 cases of achalasia indexed between 2002 and 2007. The remission was judged on Eckardt's clinical criteria. If the symptoms persist after three episodes of PD, there's a therapy failure and the patients were then proposed to surgery or recurrent DP. **The results:** The Middle Age at the time of diagnosis was of  $44 \pm 10$ , 66 years (20 to 76). The sex ratio was 1, 3 (12M/9F) ( $p = 0.5$ ). The diagnosis of achalasia is based on imaging, endoscopy and manometric arguments. The PD of the cardia was proposed in first intention, except two patients who were treated 6 and 15 years before by surgery. 38 dilations were performed for 21 patients with an average of 1.8 PD per patient [1-6]. The rate of good answers after the third episode of PD was about 90.47% (19 patients). There was no complication of the PD. In plain-varied analysis, no predictive factor of good answers to PD was retained. **Conclusion:** PD is an effective cure with a negligible morbidity and no mortality. The surgery is reserved for the failures of pneumatic dilation.

**Keywords:** Achalasia; Esophagus; Treatment; Pneumatic Dilation

## 1. INTRODUCTION

The primary achalasia of the esophagus is a rare disease known since a long time. In 1647, Thomas Willis [1] reported the first case of a patient treated for 15 years by removing the obstruction of his cardia using a rod with whalebone and a ball sponge fixed to its end. The rarity of the disease did not fully permit to understand the

pathogenic mechanisms. The most recent theories suggest autoimmune, infectious and genetic factors. The advent of esophageal manometry has allowed the diagnosis of dysphagia before without organic lesions by endoscopy and radiology. Several treatments have been proposed but none is finally healing. Pneumatic dilation (PD) and surgical cardiomyotomy are treatments that allow prolonged remission [2].

We report in this study the experience of our service on the PD as an initial treatment of achalasia. We will determine the predictors of success and failure of this treatment.

## 2. MATERIALS AND METHODS

We included all adult patients (aged over 16 years) with nonobstructive dysphagia. Our inclusion criteria were: no organic causes in the Upper gastrointestinal endoscopy. In case of doubt we have performed chest and abdominal computed Tomography. An esophageal barium transit showing a mega-esophagus. Esophageal manometry confirming the diagnosis (impaired relaxation of the LES with swallowing and/or body aperistalsis of the esophagus).

Over a period of five years (between July 2002 and December 2007), 22 cases of achalasia were identified. Clinical, endoscopic, manometric, radiological (barium esophagram), therapeutic and evolutive data were collected. These data were analyzed using Epi Info software.

All patients fasted 12 hours prior pneumatic dilation after a final liquid meal. Dilations were performed without anesthesia. An upper gastrointestinal endoscopy performed just before allowed to suck the possible esophageal stasis, to verify the absence of mucosal injury and epiphrenic diverticulum that against this procedure. This also allowed endoscopy to place the guide wire. The material used is a balloon dilator Rigiflex (Microvasive, Milford, MA, USA) in polyethylene, 10 cm in length and 30, 35 or 40 mm in caliber, a catheter 100 cm long. It slides along a metal guide wire in place during endo-

scopy before the procedure.

The first dilatation is always performed with a balloon of 30 mm in diameter. Then, if necessary with progressive diameters 35 and 40 mm. The balloon is inflated to a pressure of 10 psi, held for 30 seconds and then deflated in one minute each time, three times ( $3 \times 30$  seconds). The patients fasted 6 hours after the procedure; pulse and blood pressure were monitored every 2 hours.

Patients were routinely called a month later in consultation to assess the short-term results. The decision to perform a new expansion was based primarily on clinical criteria. Patients were asked about their current symptoms (frequency of dysphasia, chest pain, regurgitation, presence of respiratory signs, weight) and on the degree of improvement of symptoms after dilation. Success Criteria of the procedure was the decrease of Eckardt score, with a total score  $\leq 2$ , no items exceeding 2. If patients were still symptomatic after the first expansion, we perform iterative pneumatic dilation. After three sessions of expansion, if symptoms persist we consider that it was a failure of pneumatic dilation and the patient was proposed to surgery.

### Statistical Analysis

First, we conducted a clinical description of the different variables, endoscopic, radiological, manometric and therapeutic in our patients. In a second step, we performed univariate analyzes to study the effectiveness of the expansion in clinical symptoms and the factors influencing the clinical response (age, sex and initial Eckardt score). We used the Chi2 test for categorical variables and Student's t test for quantitative variables. A test was considered significant when p (significance level) was  $<0.05$ . Data entry and data analysis were performed using the Epi-Info software.

### 3. RESULTS

Twenty two patients with achalasia were included, they represented 0.47% of all patients in the Gastroenterology unit over a period of six years and six months. We excluded from our study one patient who had been treated by surgery immediately. Two patients were already known achalasic and were treated with cardiomyotomy performed 6 and 15 years ago.

The average age of patients was  $44 \pm 10.66$  years (20 - 76). The sex ratio was 1.3 for men (12H/9F) ( $p = 0.5$ ). Symptoms had begun  $36.8 \pm 34.8$  months (3 - 120 months) before diagnosis of achalasia. Dysphagia, the main symptom, was present in 100% of cases, chest pain were found in 13 cases (62%), food regurgitation in 15 cases (71.42%) and heartburn was noted in seven patients (33.33%). Respiratory signs were present in 19.04% of cases, like aspiration (4 cases) and cough (one case).

Weight loss was reported in 10 patients (47.61%) ranged from 6 to 16 kg. The Eckardt clinical score averaged was  $5.9 \pm 1.27$ . Clinical examination objectified signs of malnutrition in two patients who reported a weight loss of 11 and 16 kg each. All of its general characteristics are summarized in **Table 1**. The endoscopy showed an appearance of dilated esophagus in 52% of cases ( $n = 11$ ) and esophageal stasis in 90% ( $n = 19$ ). The cardia was crossed with jump in 81% ( $n = 17$ ). In addition, three patients had a hiatal hernia and two cases of esophagitis were observed. Barium swallow esophageal (TO) was performed in 18 patients (85.71%). The average esophageal diameter measured on this exam was  $4.30 \pm 0.89$  cm. Manometry was performed for only 16 patients (76.2%) and showed complete aperistalsis of esophageal body in all patients (100%) and a disorder of the relaxation of the LES in 93.75% ( $n = 15$ ) of cases. Mean follow-up after PD was  $7.40 \pm 6.18$  months (1 - 28 months). Two patients (9.5%) had reported heartburn after PD. No complications of dilatation were observed in our patients.

Thirty eight dilations were performed with an average PD of 1.8 per patient [1-6]. Remission after the third meeting of the PD was obtained in 19 patients (90.47%) and no patient had relapsed. The good response rate from the fourth dilatation was 50%. A fourth session was necessary in two other patients; remission was achieved in only one of them. The other patient who was 63 years old had received six sessions in total with symptomatic recurrence intervals of five months between the third, fourth and sixth expansion. These results showed that the rate of correct response after the third meeting of the PD was 90.47% (19 patients).

**Table 1.** Epidemiological and clinical characteristics of patients.

<i>Parameters</i>	<i>Patients (N = 21)</i>
<i>Age (years)</i>	$44 \pm 10.66$
<i>Sex (M/F)</i>	12/9
<i>Beginning of symptoms (months)</i>	$50 \pm 43.26$
<i>History of myotomy (%)</i>	9.5
<i>Dysphagia (%)</i>	100
<i>Regurgitation (%)</i>	71.42
<i>Chest pain (%)</i>	62
<i>Respiratory manifestations (%)</i>	19.04
<i>Loss of weight (%)</i>	47.61
Eckardt score	$5.9 \pm 1.27$
Average esophageal diameter (cm)	$4.30 \pm 0.89$
Pressure of LOS superior to 40 cm H <sub>2</sub> O	62.5%

To study the effectiveness of the PD on the clinical symptoms we compared the mean of Initial Eckardt score and one month after the third PD. The initial mean score was 5.90 and the average score after one month was 2.28, the difference was highly significant ( $p = 0.000$ ).

After univariate analysis, neither age nor sex nor the initial Eckardt score could be considered as predictive factors of failure of the PD ( $p > 0.05$ ).

#### 4. DISCUSSION

The different treatments of achalasia are palliative and aim to remove functional obstruction due to lack of relaxation of the LES to improve the quality of life for patients. Although understanding of the pathophysiological mechanisms of achalasia has progressed, pharmacological advances have been few, and medical therapy has a very modest place. According to a recent meta-analysis [2], pneumatic dilation and surgical cardiomyotomy are currently the two main treatments for achalasia that allow an early remission in 80% to 90% of cases. The objective of the PD is to create a pressure in order to suddenly dilacerate muscle of the lower esophagus, leaving intact the mucosa and serosa [2,3]. G.M. Campos *et al.* [2], in a recent meta-analysis of 15 studies of which eight were retrospective [4-11] and seven prospective [12-18] showed that the technique of balloon dilation was well

codified in these lines (**Table 2**). Thus, the choice of balloon diameter differs from one operator to another. Some of them systematically used the smallest diameter (30 mm) [4-8,10-16,19] during the first expansion, while others began with the balloon 35 mm [17,18]. In our work we used the 30 mm balloon.

The inflation pressure ranged from 7 [12,14] and 18 [5] psi, it was 10 psi in our work. The average inflation time was 73 seconds from six [16] to 240 [14] seconds. Gelfand *et al.* [12] were maintained, as in our study, the balloon inflated for 30 seconds. The number of sequences of inflation during the same dilatation varies from one to three different studies [15,20,21]. We also limited to three the number of sequences of PD during a single session.

The PD allows the improvement of symptoms in 56% [15] 97% [7] of patients assessed after one month. However, the effectiveness of the PD appears to decrease during follow-up of patients. Thus, it is around 76.8% at six months, from 68.2% at 12 months and 58.4% after 36 months follow-up [2]. In our study, 90.47% of patients were in remission three months after the PD.

The improvement of symptoms seems to depend on the diameter of the dilator, the duration of the PD and the number of PD [2]. K. Honein *et al.* [20] had achieved remission in 80.5% of cases after one or two dilatations. Concerning Diameter of the balloon, A. Dobrucali *et al.*

**Table 2.** Results of pneumatic dilation in achalasia.

Autors	Year	Patients	Type of study	Balloon diameter (mm)	Pressure psi	Follow up months	Perforation %
Gelfand [12]	1989	24	Prospective	30-35	7	6	0
Barkin [5]	1990	50	Retrospective	30-35-40	18	15	8
Kadokia [13]	1993	29	Prospective	30	8.8	48	0
Wehrmann [14]	1995	40	Prospective	30-35	7	29	3
Lambroza [6]	1995	27	Retrospective	30-35-40	15	21	0
Khan [16]	1998	81	Prospective	30	10	6	0
Sabharwal [7]	2002	76	Retrospective	20-30-40	-	29	0
Mikaeli [17]	2004	262	Prospective	30-35	10	54	1
Guardino [4]	2004	96	Retrospective	30	9.5	7	2
Dobrucali [15]	2004	43	Prospective	30	15	28	2
Chan [8]	2004	66	Retrospective	30-35-40	9	55	5
Ghoshal [19]	2004	126	Retrospective	30	11	15	1
Boztas [10]	2005	50	Retrospective	30-35-40	-	32	0
Katsinelos [11]	2005	39	Retrospective	30-35-40	-	111	5
Rai [18]	2005	56	Prospective	35	10	6	0
Our study	2008	21	Retrospective	30-35-40	10	7.40	0

[15] had noted a remission in 54% of cases with 30 mm and 78% of cases with 35 mm. Moreover, a good clinical response was observed in patients with lower sphincter pressure  $\leq 10$  mm Hg of the esophagus after PD or in whom it has fallen by over 50% of the initial pressure [11,22]. In case of failure of the expansion, it is repeated several weeks later (four in our work) with a balloon of larger diameter. In case of repeated failures, most authors agree not to exceed three expansions [15,20,21] after which the patient was proposed for another treatment. The PD is currently the most effective endoscopic treatment of primary achalasia of the esophagus. The esophageal perforation is the most serious complication. However it is reported in only 1.6% of the average [2]. In our series, there was no perforation.

Surgical treatment of achalasia has evolved dramatically over the past 13 years. Since the first report of laparoscopic Heller myotomy in 1991 by Cuschieri [23] and thoracoscopic Heller myotomy by Pellegrini [24] in 1992, minimally invasive surgery has become the gold standard for the treatment of achalasia. More recently, the laparoscopic management of esophageal achalasia has achieved widespread acceptance and is now the first line of therapy for patients with achalasia. The satisfactory short-term results of this procedure are well documented in several large series [23-25]. In these studies, persistent postoperative dysphagia was observed in 10% to 30% of the patients. Patients with LES pressure  $> 35$  mmHg had more than 21 times the likelihood to achieve long term excellent relief of dysphagia after myotomy compared with those with LES pressure  $\leq 35$  mmHg. This finding probably means that patients with a low preoperative LES pressure did not get as much relief because their relative decrease in outflow obstruction is less.

## 5. CONCLUSION

Pneumatic dilation can be proposed as a first-line treatment of primary achalasia of the esophagus, it allows a short-term clinical remission in 90.47% of cases, and long-term in only 50% supporting iterative expansions. Age was not predictive of poor response to the PD in our work; however, other studies are needed to confirm this result.

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