

## Original Article

## Clinical Outcome of Pneumatic Dilatation in Patients with Achalasia Cardia: A Single-Center Prospective Study

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**ABSTRACT** **Background and Aim:** Pneumatic balloon dilation is one of the most commonly used and effective methods for treating patients with achalasia cardia. This study was performed to assess immediate and long-term response of pneumatic dilatation (PD) in these patients. **Materials and Methods:** Forty-four achalasia cardia patients, who underwent PD in our center from January 2013 to December 2015, were prospectively studied. Data from these patients were analyzed for clinical improvement in symptoms after dilatation procedure over this period as per Eckardt score. Patients who required repeated procedure and factors influencing remission of symptoms were analyzed. **Results:** A total of 44 patients underwent PD, among which three lost to follow up. Of the 41 patients, 21 were male (51.22%) and 20 were females (48.78%). Mean age was 38.68 (13–64) years. Median symptom duration before first dilatation was 18 months (2–240). Major symptoms at presentation were dysphagia ( $n = 41$ , 100%), regurgitation ( $n = 38$  92.68%), chest pain ( $n = 31$ , 75.6%), and weight loss ( $n = 20$ , 48.78%). Mean follow-up period was 22.22 months (9–38). Forty (97.56%) patients had immediate clinical improvement after 1 dilatation, of which 38 (92.68%) patients did not require any further treatment. Mean Eckardt score was 6.82 (4–11) at the time of first dilatation which improved to 0.66 during follow-up. Two patients required second dilatation (one 5 months and other 18 months after the first procedure). **Conclusion:** PD is a safe and effective long-term therapy for achalasia cardia and has a good long-term clinical remission.

**KEYWORDS:** Achalasia cardia, Eckardt score, pneumatic dilatation

## INTRODUCTION

Achalasia cardia is a primary esophageal motor disorder of unknown etiology, caused by degeneration of neurons in the wall of the esophagus, leading to the absence of peristalsis and impaired relaxation of the lower esophageal sphincter (LES). It is characterized by dysphagia, regurgitation of undigested food, chest pain, and weight loss.<sup>[1,2]</sup> Radiologically, it is characterized by aperistalsis, esophageal dilation, minimal LES opening with a “bird’s beak” appearance, and poor esophageal emptying of barium.<sup>[3]</sup>

Achalasia is a chronic condition with only treatment option being to reduce LES pressure. This can be achieved by pharmacological methods (nitrates and calcium channel blockers), botulinum toxin injection, pneumatic balloon dilatation, surgical Heller myotomy,

and recently by, peroral endoscopic myotomy (POEM). Pharmacological methods and botulinum toxin are less followed due to limited and short-term response rates. Pneumatic balloon dilatation and surgical myotomy are considered to have best long-term treatment response, with POEM considered as emerging treatment option for long-standing achalasia, sigmoid esophagus, in patients with previously failed endoscopic or surgical treatment and other spastic esophageal motility disorders.<sup>[4,5]</sup> However, POEM is limited by high cost, technical expertise, availability, lack of long-term data,

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and complications rate as compared to PD. In one of a landmark study, the rate of therapeutic success with PD was 90% after 1 year of follow-up and 86% after 2 years, as compared to 93% and 90% after 1 and 2 years of follow-up with Heller myotomy.<sup>[6]</sup> Although these treatment modalities reduce LES pressure gradient and thereby reducing patients' symptoms, they are not curable, and recurrence of disease is inevitable.

Pneumatic dilatation (PD) is considered as first-line efficient and safe nonsurgical therapy in most of centers. The principle of this procedure is to weaken the LES by generating radial force around the sphincter. There are both high and low compliance balloon dilators, designed to distend the LES to a diameter of 30–40 mm, thereby disrupting the sphincteric muscle. Rigiflex balloon (Boston Scientific, Boston, MA, USA), which comprises a polyethylene balloon at the distal end of a catheter, is the most commonly used type. Most studies have shown an acceptable clinical remission rate of 54%–91% with PD.<sup>[7,8]</sup> Complications associated with PD include intramural hematoma, diverticula at the gastric cardia, mucosal tears, prolonged postprocedure chest pain, reflux symptoms, and rarely perforation, which is the most feared complication occurring in around 0.3%–3.3%.<sup>[8]</sup>

Gender, age, and postdilatation LES pressure are important prognostic factors determining success rate following PD. Most of studies have used single setting PD followed by reevaluation after 1 month with Eckardt's symptoms scoring. However, there are mixed results on long-term therapeutic outcome after PD.

This study was undertaken to prospectively evaluate the immediate and long-term results of PD for achalasia in our center, over a period of 3 years.

## MATERIALS AND METHODS

The study was undertaken in Medical college, Kozhikode, between January 2013 and December 2015. All patients with a diagnosis of achalasia cardia by clinical features, barium swallow, endoscopic, and/or manometric features suggestive of achalasia, who underwent PD with Rigiflex balloon dilators were prospectively studied. Patients with structural esophageal lesions such as stricture, malignancy (pseudoachalasia), previous history of surgery, PD, or POEM were excluded from the study.

### Initial evaluation and follow-up

The pretreatment evaluation of patient included symptom assessment, endoscopic evaluation to rule out pseudoachalasia and other structural causes, barium swallow, and manometry when available. Symptoms were scored using the Eckardt score, which is the sum of

the scores for dysphagia, regurgitation, and chest pain on a scale from 0 to 3 (0 = absent, 1 = occasional, 2 = daily, and 3 = each meal) and weight loss (0 = no weight loss, 1 ≤ 5 kg, 2 = 5–10 kg, and 3 ≥ 10 kg).<sup>[9]</sup>

Patients were followed up 1 month after the initial treatment, 6 monthly thereafter, and at the time of symptom recurrence. Symptoms were assessed with Eckardt score at regular intervals during follow-up.

Patients were considered to have a good clinical response if symptoms had totally disappeared or if they had improved by at least two points and did not exceed a score of 3 on Eckardt score. Patients who had a recurrence of symptoms were considered as treatment failures.

### Esophageal manometry

High-resolution manometry (HRM) was performed with a 16 channel water perfused catheter. The procedure included a basal LES pressure recording for 3 min, followed by ten 5 mL wet swallows. HRM was performed at the time of diagnosis. Achalasia was diagnosed as an impaired LES relaxation on deglutition (mean integrated relaxation pressure ≥15 mmHg) and aperistalsis of the esophageal body. Achalasia was subdivided into three types based on manometric findings. Type I achalasia (classic achalasia) was considered when the distal esophageal pressure was <30 mmHg in at least 20% of the swallows. For Type II achalasia (achalasia with esophageal compression), at least two out of the ten wet swallows should be associated with a panesophageal pressurization >30 mmHg, and in Type III achalasia (spastic achalasia), there should be two or more spastic contractions (contractile front velocity >8 cm/s) with or without periods of compartmentalized pressurization.<sup>[10,11]</sup>

Pneumatic balloon dilatation was performed with a Rigiflex (Boston Scientific Corporation, Boston, MA, USA) achalasia balloon dilator. A 30 mm balloon, which is connected to a pressure gauge, is progressively inflated for a pressure of 10 psi and maintained in that pressure for a period of 1 min.

The primary endpoint of the study was a recurrence of symptoms of dysphagia, regurgitation, chest pain, or weight loss during follow-up after PD and to determine the requirement of repeat dilatation procedure based on Eckardt score.

### Statistical analysis

The data were analyzed using SPSS version 18 (Released 2009, PASW statistics for windows, version 18.0, Chicago, USA: SPSS, Inc.). Paired *t*-tests were used to compare Eckardt score between different timelines. Mean

and median were used for variables such as symptoms, age, and other paired data. ANOVA test was used to compare results between different HRM subtypes.

## RESULTS

Fifty-two patients were initially evaluated for symptoms for dysphagia in the study period. These patients underwent barium swallow and upper gastrointestinal endoscopy initially. Eight patients were later excluded from the study (four had esophageal malignancy, two had a peptic stricture, and two were previously treated for PD). Forty-four patients underwent dilatation, among which three patients lost to follow up, and so final evaluation was carried out in 41 patients.

Out of 41 patients, 21 were men and 20 were women. Type 1 achalasia was present in five patients, Type 2 in 21, and Type 3 in 3 patients, whereas 12 patients did not have manometric study before dilatation, and in them, achalasia was diagnosed based on typical radiologic finding and endoscopy study. Mean age was 38.68 (13–64) years. Symptoms at presentation were dysphagia ( $n = 41$ , 100%), regurgitation ( $n = 38$  92.68%), chest pain ( $n = 31$ , 75.6%), and weight loss ( $n = 20$ , 48.78%) as depicted in Table 1. Median symptom duration before dilatation was 46.17 months (2–240). Thirty-eight patients underwent single dilatation procedure whereas two patients required two dilatation procedures.

Patients had minor complaints such as occasional retrosternal chest pain (in 26.83%), regurgitation (in 34.15%) following the dilatation procedure, which was managed medically. Only one patient complained of reflux symptoms during the first follow-up at 1 month after procedure, which subsided during further follow-up. One patient had a perforation following achalasia, who subsequently underwent surgery and was asymptomatic at the end of the study period.

### Treatment: Short-term outcome

Forty (97.56%) patients had immediate clinical improvement after initial dilatation, of which 38 (92.68%)

patients did not require any further treatment. One patient had perforation following dilatation and required surgery. Mean Eckardt score was 6.85 (4–11) at the time of first dilatation which improved to 0.56 (0–3) at first follow-up at 1 month and 0.61 (0–3) at the time of analysis at last follow-up. Postdilatation symptoms' score of dysphagia, chest pain, regurgitation, and weight loss was also significantly decreased at 1-month follow up ( $P < 0.001$  Students paired  $t$ -test) as shown in Table 2.

### Treatment: Long-term outcomes

Mean follow-up period was 22.22 months (9–38). Mean Eckardt score at the end of follow-up was 0.61. All patients were followed up on the basis of symptoms, and no manometry was carried out after dilatation procedure. During follow-up period, two (4.8%) patients required second dilatation; one 5 months and other 18 months after first procedure due to recurrence of symptomatic dysphagia. Both the patients were symptom free after second PD.

## DISCUSSION

The study was conducted from a tertiary care center in southern India to assess the clinical outcome of achalasia cardia. This study shows that the long-term clinical response to PD is better than previous literature with minimal adverse events and requiring fewer dilatation sessions in the majority of cases. Majority of patients were under clinical remission - 92.6% under a mean follow-up of 22.2 months. Previous studies show a response rate of 59%–93% for PD.<sup>[12,13]</sup> A study conducted by Chuah *et al.*, where patients after PD were prospectively studied for 7 years, showed a remission rate of 80% after 3 years and 61.7% after 7 years.<sup>[14]</sup> Another study from India showed a response rate of 81% after a median follow-up of 20 months.<sup>[15]</sup> However, few of studies show contradicting results, questioning the role of PD on a long run.<sup>[12,16,17]</sup> However, these data have few drawbacks of being retrospective studies, lack of definite clinical criteria to define symptom improvement, and variations in duration of follow-up. Complication rates

**Table 1: Baseline characteristics, symptom complex, and follow-up duration in various achalasia patients**

	Type I	Type II	Type III	No manometric findings	Statistical significance (ANOVA between groups)
Age (years)	39	34.6	47.6	43.3	0.207
Gender (male/female in percentage)	20/80	57.1/42.9	66.7/33.3	41.7/58.3	NA
Mean duration of symptoms (months)	49.2	36.1	28.6	66.9	0.576
Dysphagia (months)	49.2	34.9	28.6	66.9	0.554
Chest pain (months)	1.4	14.5	2.3	9.9	0.710
Regurgitation (months)	13	9.1	6.3	29.5	0.479
Weight loss	2.4	7.1	3	2	0.424
Symptom free duration (months)	29.6	21	12.3	23.25	0.019

NA=Not available

**Table 2: Eckardt score at baseline and during follow up**

	Mean Eckardt score	SD	ANOVA between groups
Eckardt score baseline			
Manometry not available	8.00	2.132	0.065
Type 1 achalasia	6.80	0.837	
Type 2 achalasia	6.38	1.774	
Type 3 achalasia	5.67	0.577	
Total	6.85	1.878	
Eckardt score 1 month follow-up			
Manometry not available	1.42	1.240	0.000
Type 1 achalasia	0.60	0.548	
Type 2 achalasia	0.14	0.359	
Type 3 achalasia	0.00	0.000	
Total	0.56	0.923	
Eckardt score at last visit			
Manometry not available	1.08	0.669	0.029
Type 1 achalasia	0.80	0.837	
Type 2 achalasia	0.38	0.740	
Type 3 achalasia	0.00	0.000	
Total	0.61	0.771	

SD=Standard deviation

following PD were minimal and comparable to previous studies.<sup>[12,13,16]</sup>

PD was carried out in all types of achalasia in this study, and all types showed a favorable response. This is important, especially in developing countries where manometry may not be available in all centers, and treatment is decided solely on the radiological and endoscopic evidence. Studies have clearly shown the better response for PD with Type II achalasia and POEM being considered successfully for other types.<sup>[18,19]</sup> However, POEM is yet to be available in all centers due to high cost and technical expertise.

Even in this era of third space endoscopy, PD and Heller myotomy remains as the best treatment options in developing countries. Among surgical and PD, surgery poses a definitive higher morbidity, cost, and complication rate with almost comparable long-term efficacy rates. Considering symptoms as the only factor to determine clinical remission is also a very practical approach, especially in centers where manometry is not available.

Furthermore, determining various factors in treatment success helps in planning follow-up of this chronic condition. One of the initial studies from Southern India showed that nonresponders were more often younger than 40 years of age, had LES pressure >50 mmHg, and midesophageal hypocontractions.<sup>[15]</sup> This study showed no statistically significant factors determining treatment success. This could be due to a negligible number of treatment failure in the study.

The drawbacks of this study were relatively short follow-up period and absence of objective (manometric) evaluation during follow-up. However, we included uniform treatment and follow-up modality in all types of achalasia patients.

## CONCLUSION

Achalasia is yet to have a defined optimization in treatment duration and requires tailoring treatment options on a case-to-case basis. Although there are various determinants such as age, gender, postdilatation LES pressure, duration of symptoms before diagnosis, and dilated esophagus which determines outcome following PD, it is very difficult to determine recurrence in them. This prospective study shows that all three types of achalasia have a better outcome following single dilatation session and also had a good long-term remission.

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## Conflicts of interest

There are no conflicts of interest.

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