

## ORIGINAL ARTICLE

# Effect of Pneumatic Balloon Dilation on Changes of Eckardt Score Among Patients with Achalasia

Budi Widodo<sup>1\*</sup>, Iswan Abbas Nusi<sup>1</sup>, Titong Sugihartono<sup>1</sup>

<sup>1</sup>Department of Internal Medicine, Faculty of Medicine, Universitas Airlangga - Dr. Soetomo General Hospital, Surabaya, Indonesia

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## ABSTRACT

**Introduction:** Achalasia is an esophageal motility disorder, but its pathogenesis remains unclear. The highest incidence is among adults aged 30 – 60 years with the prevalence of 10/100.000 population. Diagnosis of achalasia is based on symptoms and upper endoscopy, barium esophagogram, and esophageal manometry. Pneumatic Balloon Dilation (PBD) is one of the treatment options, whether it is fluoroscopy-guided or direct endoscopy guided. This study aims to analyze the effect of PBD on the changes of Eckardt score among achalasia patients.

**Methods:** An analytical observational study with a retrospective and prospective design was conducted on 18 achalasia patients who performed PBD at Dr. Soetomo General Hospital. Data were then analyzed using t-test.

**Results:** The mean age was 47.8±12.5 years, and the mean achalasia duration was 18.3±5.9 months. There were no differences of achalasia cases between men and women. The mean body weight in the pre and post PBD was 50.9±6.2 vs 53.1±6.5 kg with delta 2.19±1.88 (p <0.0001). The mean BMI in the pre and post PBD was 20.2±2.2 vs 21.1±2.5 kg/m<sup>2</sup> with delta 0.89±0.78 (p <0.0001). In addition, the mean Eckardt score in the pre and post PBD was 10.17±1.47 vs 2.5±0.86 (p <0.0001). There were 3 patients with Eckardt score of 4 after PBD and no weight loss after one-month evaluation.

**Conclusion:** There was a significant difference of Eckardt score before and after PBD. The improvement of the Eckardt scores led to the change of weight and body mass index among achalasia patients.

## Introduction

Achalasia in Greek means no relaxation. It is a disease that has no exact cause and characterized by the loss of peristalsis in the distal esophagus and the failure of lower esophageal sphincter relaxation (Lower Esophageal Sphincter/LES) during swallowing.<sup>1</sup> Incidence of achalasia is estimated to be 1-1.6 out of 100,000 population with a prevalence of around 10 out of 100,000 population. There is no incidence rate difference between certain races or ethnicity and gender. The highest incidence is at the age of 30 and 60 years.<sup>2,3</sup> Data from the Division of Gastroenterology, Department of Internal Medicine, Faculty of Medicine, University of Indonesia/Cipto Mangunkusumo Hospital found 48 cases in a period of 5 years (1984-1988), which mostly occurred in middle age and almost same ratio between gender.<sup>4</sup> Whereas, there is no data regarding achalasia at Dr. Soetomo General Hospital, Surabaya.

The pathogenesis of achalasia is still unknown. Suspected motor abnormalities and LES recalcitration disorders are accompanied by peristalsis due to hereditary abnormalities, autoimmune diseases, and infectious factors. This situation causes an increase in

LES pressure, and thus solid and liquid food cannot enter the stomach.<sup>5,6</sup> The disorders are often found in forms of difficulty swallowing solid food (91% of cases) and liquid food (85% of cases), difficulty belching (85% of cases), and other complaints, such as weight loss, regurgitation, chest pain, and chest burning sensation which occurs around 40 -60%.<sup>3</sup>

Diagnosis of achalasia can be examined by clinical symptoms such as difficulty swallowing, retrosternal pain, regurgitation, weight loss and is confirmed by an esophagogram, endoscopy, and manometry.<sup>7</sup> The management of achalasia aims to reduce the pressure on the LES. The treatments are drugs, endoscopic approach, and surgery. One of the current therapies options is pneumatic balloon dilatation (PBD) which aims to make tears in the mucularis propia layer, with a 90% success rate in the first year and 86% in the second year. This dilatation action can be done with or without fluoroscopic guidance.<sup>8,9</sup> Levine and colleagues investigated the safety and comfort of using PDB techniques with endoscopic guidance without the use of fluoroscopy.<sup>10</sup> PDB performed at Dr. Soetomo General

\*Correspondence: widodobudi7319@gmail.com

Hospital are using no fluoroscopic guide.

The success of achalasia therapy can be seen through symptoms that patients experience or by some modalities. Some researchers recommend symptom monitoring to determine the success of therapy by using Eckardt. Eckardt scores of less than 3 are classified into a successful therapy, scores of more than 4 are classified into recurrences, and scores of more than 6 are classified into recurrences that require action.<sup>8</sup> Besides, monitoring also can be done by manometry examination by looking at the-pressure on the LES and barium esophagogram periodically.<sup>2</sup> Research conducted by using Eckardt score obtained 90% of 95 patients in the first year and 86% of 95 patients who had pneumatic balloon dilatation had a score below 3, while patients who underwent Heller's myotomy surgery obtained 93% in the first year and 90% in the second year had a score below 3.<sup>9</sup> Based on the afore mentioned issues, we focused on analyzing pneumatic balloon dilatation effects among patients with achalasia.

### Methods

This research was a prospective analytical study. This study analyzed the effect of balloon dilatation on the changes of Eckardt scores among achalasia patients. The study was conducted in the inpatient room and endoscopic room in the Internal Medicine Unit of Dr. Soetomo General Hospital, Surabaya. The study design and protocol were approved by the Ethics Committee of Dr. Soetomo General Hospital, Surabaya (726/Panke. KKE/XII/2017).

The study population was all patients with achalasia that hospitalized in inpatient room and endoscopy room in the Internal Medicine Unit of Dr. Soetomo General Hospital, Surabaya, while the samples were achalasia patients underwent treatment from July 1, 2016 to June 30, 2017. The exclusion criteria were incomplete medical records, diagnosis of malignancy in the esophagus, and having a chronic illness such as and cirrhosis.

This study used secondary data (medical records) and primary data (endoscopy result). The independent variables in this study were pneumatic balloon dilatation, barium esophagus, and endoscopy, while the dependent variable was the change of Eckardt score. The analysis was performed using SPSS statistical software version 21.0. Quantitative variables were presented as mean value  $\pm$  standard deviation for continuous variables or percentages for categorical variables. While the inferential analysis used the t-test to determine changes in Eckardt scores. Two-tailed test with  $p < 0.05$  was considered statistically significant.

### Results

The number of subjects was 18 patients with achalasia in the inpatient room and endoscopy room at Dr. Soetomo General Hospital Surabaya. The characteristics of the subjects are shown in table 1.

Table 1. Characteristics of the subjects

Characteristic	n (%) (n=18)
Age (years old)	
Mean $\pm$ SD	47.8 $\pm$ 12.5
Median	23-46
Sex	
Male	9 (50%)
Female	9 (50%)
Duration of achalasia (month)	
Mean $\pm$ SD	18.3 $\pm$ 5.9
Median (range)	12-24
Treatment	
Yes	8 (44.4%)
No	10 (55.6%)
Barium Esophagus	
Mild	8 (44.4%)
Sever	10 (55.6%)
Endoscopy	
Normal	0
Dilatation	10 (100%)
Weight Loss	
<5 kg	5 (27.8%)
5-10 kg	8 (44.4%)
10-15 kg	5 (27.8%)
Complication after Dilatation	
Pain	4 (22.2%)
Perforation	0

The mean age was 47.8 $\pm$ 12.5 years with the youngest age of 23 years and the oldest of 66 years. The sex ratio was the same between gender. The mean duration of suffering achalasia disorder was 18.3 $\pm$ 5.9 months with the shortest duration of 12 months and the longest duration of 24 months. Most of the subjects (55.6%) did not get treatment, but 8 patients (44.4%) got pharmacological treatment.

All patient showed esophageal dilatation from endoscopic examination and barium swallow examination discovered there was 44.4% of the subjects had mild esophageal dilatation and 55.6% with severe dilatation. The evaluation of pain after measuring dilation 77.8% of patient did not get any complaints of pain after performing pneumatic balloon dilatation, whereas patients with pain had been given analgesic. We classified weight loss into 3 groups. There was 44.4% of patient had weight loss between 5-10 kg.

Table 2 shows the result of statistic analysis was done by using a T-test to measure changes in the Eckardt score before and after performing PBD. The Eckardt score was 10.17 $\pm$ 1.47 before PBD and 2.5 $\pm$ 0.86 after PBD with  $p < 0.0001$ . The improvement of the Eckardt score caused changes in weight and body mass index with  $p < 0.0001$ .

Table 2. Analysis of weight and BMI towards changes of eckardt score

Characteristic	Before	After	Delta	p
Eckardt Score	10.17±1.47	2.5±0.86		<0.0001
Weight (kg)	50.97±6.27	53.16±6.58	2.19±1.88	<0.0001
BMI	20.27±2.27	21.16±2.59	0.89±0.78	<0.0001

## Discussion

A study by Bravi et al. (2010) examined 77 patients with achalasia who had pneumatic balloon dilatation, and 14 patients were excluded from the study because of Heller cardiomyotomy. They found 77 patients with the age range of 51 years (31-64 years), the sex ratio of 43 men (56%) and 33 women (44%). The duration of achalasia before being diagnosed was 2.5 years (1.3-6.0 years). A perforation as complication occurred to 1.7% of 91 patients who performed pneumatic dilatation using a 30 mm balloon during the first dilatation and a 35 mm balloon during the second dilatation.<sup>11</sup> While Wang et al. (2015) reported 21 subjects consisting of 13 male (61.9%) and 8 female (38.1%); the mean age was 49.9 years (18-93 years). The complication was minor bleeding that occurred to 2 subjects (9.5%), and the drug treatment was given to relieve the complication.<sup>12</sup>

In this study, the mean body weight after one month dilatation was slightly increase. This is due to pressure decreasing on the LES because of the esophageal lamina propria damage as the results of pneumatic balloon dilatation. This condition makes it easy for food to enter the stomach. This result was in line with previous study that reported the mean change in body weight after one year observation was 2.1 kg (1.4-2.6 kg).<sup>12</sup>

This study used Eckardt scores with the mean of 10.17 before dilatation and 2.5 after one-month dilatation. The Eckardt score component was obtained consecutively before and after PBD as following weight loss of 2.0 kg (2-3 kg) versus 0 (0); dysphagia 2.7 kg (2-3 kg) versus 0.8 kg (0-2 kg); retrosternal pain 2.6 kg (2-3 kg) versus 0.8 kg (0-2 kg) and regurgitation 2.6 kg (2-3 kg) versus 0.8 kg (0-1 kg). In line with this, Boeckxstaens *et al.* (2011) found that the average Eckardt score before dilatation was 7 (4-10), 1.4 (0-3) after one-year dilatation and 1.5 (0-4) after two-year dilatation.<sup>9</sup> Whereas, Bravi *et al.* (2010) reported Eckardt score before dilatation was 7 (4.5-8.0), and Eckardt score was 1 (1-2) after six-year dilatation. They also obtained three patients with Eckardt scores of 4.4 and 5. The Eckardt score components before dilatation were respectively weight loss 1.5 (0-2), dysphagia 3 (2-3), retrosternal pain 1 (0-1.5), and regurgitation 1 (0.5-2).<sup>11</sup> While Wang *et al.* (2015) reported before the Eckardt score was obtained, the Eckardt score of 4-5 occurred to 0 patients, of 6-7 to 12 patients (57.1), and of 8-9 to 9 patients (42.9), and after the action under six-week observation improvements were found in the Eckardt scores with a median of 5 (4-6).<sup>12</sup>

This study found a significant improvement in the Eckardt scores after PBD was performed. This study pointed out that 15 subjects (83.3%) experienced remission after PBD with the Eckardt score <3, and it found 3 subjects (16.7%) had failed therapy with the Eckardt score of 4. The subjects with the Eckardt score of 4 gained weight in one-month monitoring but still had complaints, such as dysphagia, retrosternal pain or regurgitation. This might be

influenced by the subjectivity of the research subjects.

Boeckxstaens et al. (2011) declared the success of the dilatation action with the Eckardt score  $\leq 3$ . Four patients failed in the dilatation therapy because the Eckardt score did not change at  $\leq 3$  and needed repeated dilatation.<sup>9</sup> Another study reported that 6-year observation of Stable Clinical Remission (SCR) discovered the Eckardt score of 1 (1-2) in 69 patients. As many as 55 patients were performed one dilatation, and 14 patients were performed double dilatation. Eight patients did not achieve SCR after two dilatations, and thus cardiomyotomy was performed. In 14 patients who did two dilatations, the LES pressure was higher than in 69 patients who underwent one dilatation.<sup>11</sup>

Research conducted by Rai et al. (2005) reported that after six-weeks PBD, 52 patients (92.9%) had very good responses, 2 patients (3.6%) had good responses, and 2 patients (3.6%) with poor therapeutic responses.<sup>13</sup> The patients were re-dilated after the second dilatation gave good results. Wang et al. (2015) reported 21 patients (100%) experienced remission after PBD action.<sup>12</sup>

## Conclusion

There was a significant difference in patient's Eckardt score after PBD treatment. Most of the patient had score <3 in which led to the change of weight and body mass index.

## Conflict of Interest

The author stated there is no conflict of interest

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