# Original article

# Outcome of pneumatic balloon dilatation of lower oesophageal sphincter of oesophagus of patients suffering from achalasia cardia

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#### Abstract

Achalasia is an oesophageal motility disorder of unknown cause, primarily characterized by absence of peristalsis of the esophageal body and impaired relaxation of lower oesophageal sphincter resulting invariably in dysphagia for solids/liquids or both and regurgitation of undigested foods. The diagnosis is usually made by classical symptoms, barium swallow X-ray of oesophagus or by endoscopy. Goal of treatment is to relieve symptoms, improve esophageal emptying and reduce the risk of associate complications. The two most successful treatment options are pneumatic dilation of lower oesophageal sphincter and surgical myotomy. This quasi-experimental study was carried out from January 2010 to December 2011 involving 31 patients of Achalasia Cardia admitted in the Department of Gastroenterology of BSMMU, Dhaka who underwent pneumatic balloon dilatation. Immediately after pneumatic dilatation all the patients got relief of dysphagia and were discharged from hospital next day. At follow-up 4 weeks after pneumatic dilatation, majority (96.2%) of the patients remained improved symptomatically. Significant weight gain was also found at 4 weeks after pneumatic dilatation.

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Pneumatic dilatation came out to be a simple, safe and effective method for treating patients with achalasia cardia.

**Key words:** Achalasia cardia, pneumatic dilation, dysphagia, myotomy.

#### Introduction

Achalasia cardia is a motility disorder, primarily characterized by abnormal or absent relaxation of the lower oesophageal sphincter (LOS). More specifically, it is a neuromuscular disorder characterized by degenerative changes of the myenteric plexus leading to a selective loss of inhibitory nerve endings. Irreversible disruption of peristaltic contractions and impaired relaxation of the lower esophageal sphincter in response to deglutition are the consequences of this damage. This condition, regardless of its cause, ultimately results in abnormal transit of oesophageal contents from the distal oesophagus into the stomach and progressive oesophageal dilatation.

Primary idiopathic achalasia cardia is a quite rare disease, with an incidence of approximately 1/100,000/year and a prevalence rate of 10/100,000.<sup>2</sup> Primary achalasia cardia in children is part of the Allgrove's and Alport's syndromes, and is more frequent in Down's syndrome.<sup>2</sup> Secondary achalasia cardia shares clinical features with primary achalasia cardia, but there is always an identifiable cause.<sup>3,4</sup>

From the clinical point of view, achalasia cardia is a progressive disease that presents with symptoms of dysphagia both for liquid and solid foods, chest pain and regurgitation of undigested foods that occurs during meals, shortly thereafter or hours later when the patient changes into the recumbent position. Aspiration of food from the oesophagus may lead to pneumonia. Loss of weight and malnutrition are uncommon, but they may occur in advanced disease and in elderly patients.<sup>5</sup>

Restoration of muscular activity and reversal of oesphageal aperistalsis is rarely reversed by any mode of treatment. Therefore, every treatment for achalasia cardia is directed at reducing the gradient across the lower oesphageal sphincter (LOS) with three goals: 1) relieving patient's symptoms, especially dysphagia and regurgitation, 2) improving oesophageal emptying and 3) reducing associated complications.

In the modern era of achalasia cardia treatment, disruption of LOS is best accomplished by pneumatic dilatation using the Pneumatic balloon dilator or laparoscopic myotomy. It is less effectively treated with pharmacological agents, such as botulinum toxin injection or calcium channel blockers. Symptom of dysphagia and regurgitation are easier to treat, but chest pain relief is more unpredictable.<sup>6</sup> Overall, using single or multiple modalities of treatment, over 90% of patients remain well.<sup>7</sup>

Pneumatic dilatation aims at disrupting the LOS by forceful stretching using air-filled balloons. In an updated review through 2009 of 1144 patients across 24 studies with an average follow up of 37 months, pneumatic dilatation using rigiflex balloon in a graded fashion gave good to excellent symptom relief in 74%, 86% and 90% treated with the 3.0, 3.5 and 4.0 cm balloon, respectively.<sup>3,8</sup> Over a third of treated patients experienced symptom relapse over 4-6 years of follow-up.9-11 The risk factors for relapse after pneumatic dilatation are mainly young age (< 40 years), male gender, single dilatation with a 3.0 cm balloon, post-treatment LOS pressure >10-15 mm Hg and poor oesophageal emptying on an upright barium oesophagram (timed barium swallow). 6,9,12,13,14 Pneumatic dilatation is the most cost-effective treatment for achalasia cardia over a time period of 5 to 10 years. 15,16

The only absolute contraindication to pneumatic dilatation is poor cardiopulmonary status, or other co-morbid illnesses preventing surgery. Complications after pneumatic dilation are reported in up to 33% of patients with most complications being minor.<sup>3</sup> Oesophageal perforation is the most serious complication after pneumatic dilatation with an overall rate in experienced hands of 1.9% (range 0-16%). Most perforations occur during the first dilatation, with difficulty in keeping the balloon in position during the procedure as potential risk factor.<sup>17</sup> Severe complications i.e. GORD are rare after pneumatic dilatation, but 15-35% of patients have heartburn responding to proton pump inhibitors.<sup>3</sup> Other usually minor complications after pneumatic dilatation include chest pain, aspiration pneumonia, bleeding usually without a decrease in haemoglobin, transient fever, oesophageal mucosal tear without perforation and oesophageal haematoma.

The prognosis of patients suffering from achalasia cardia regarding returning to near-normal swallowing and good quality of life following pneumatic dilatation are excellentwith a single session of dilatation, though intermittent "touch up" procedures may be required. But

there is paucity of study conducted in the context of our population. Only one study was conducted in Bangladesh on 17 patients of achalasia reporting clinical presentation and outcome of management. So the proposed study, intended to find the outcome of pneumatic dilatation in patients with achalsia cardia seems to be justified. The data derived from the proposed study would be helpful to develop a comprehensive understanding about the life of the patients after the treatment and also helpful to guide the physicians in taking decisions about treatment of choice from the various treatment options for the management of achalasia cardia in our population.

#### Methods

This quasi-experimental study was carried out from January 2010 to December 2011 involving 31 patients of Achalasia Cardia admitted in the Department of Gastroenterology of BSMMU, Dhaka. Patients attending in the Department of Gastroenterology of BSMMU with the classical symptoms of achalasia cardia who underwent pneumatic dilatation were initially included in the study, based on predefined enrollment criteria. After proper explanation written informed consent were obtained from the selected patients for upper GI endoscopy and pneumatic balloon dilatation. Selected patients underwent the procedure in the Department of Gastroenterology, BSMMU using an Olympus forward viewing video endoscope and Rigiflex balloon dilator. During the procedure aseptic precaution were adopted and the same technique were followed and maintained for each patient.

Overall post-procedure observation period was 4-6 hrs to exclude perforation and evaluate for chest pain and fever. After 6 hrs of observation, patients were allowed to drink fluids. Patients with pain during this observation period were checked for any complications. If no complication, patients were discharged home next day with instructions to attend the follow up clinic 2 – 4 weeks thereafter. In the follow up clinic, symptoms and oesophageal function, specially oesophageal emptying were assessed. A barium swallow X-ray of oesophagus and/or endoscopy was performed in case of any suspicion of complication.

Data were processed and analyzed using SPSS (Statistical Package for Social Sciences) version 11.5. Test statistics used to analyses the data were descriptive statistics, McNemar Chi-square ( $\chi^2$ ) and Willcoxon Signed Rank Test. The level of significance for any analytical tests was set at 0.05 and p <0.05 was considered significant.

## Results

Demographic characteristics of the patients show that 16.1% of the patients were < 20 years old, 22.6% 22-30

years, 22.6% 30 - 40 years, 29% 40 - 50 years and 9.7%  $\geq 50$  years old. The mean age of the patients was 34 years and youngest and oldest patients were 8 and 70 years old respectively. Male female ratio was almost 1:1.

Distribution of patients by their body mass index demonstrates that over half (51.6%) of the patients was underweight (BMI < 18.5 kg/m2) (Figure-1).

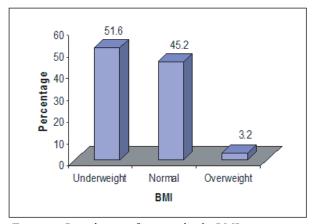


Figure-1: Distribution of patients by the BMI

Mode of clinical presentation shows that dysphagia for solids or liquids and regurgitation of undigested food were invariably complained by the patients. Majority (96.8%) of the patients experienced weight loss followed by chest pain (87.1%), nocturnal cough and halitosis (each 67.7%), hiccup (38.7%) and symptoms of pneumonia (25.8%) (Table-I)

**Table-I:** Distribution of patients by their presenting symptoms

Clinical presentation	Frequency	Percentage
Dysphagia for solids/liquids	31	100
Regurgitation of undigested food	1 31	100
Weight loss	30	96.8
Chest pain	27	87.1
Nocturnal cough	21	67.7
Halitosis	21	67.7
Hiccup	12	38.7
Symptoms of pneumonia	08	25.8

On endoscopic examination 38.7% cases exhibited peristaltic movement. Over half (52%) of the patients contained small amount, 24% moderate amount and another 24% huge amount of food in the oesophagus. In 50% of the cases, the lower oesophageal sphincter was observed to be moderately constricted, in 25% cases severely constricted and in another 25% cases mildly constricted (Table-II)

Table-II: Endoscopic findings of upper gastrointestinal tract

Endoscopic findings	Frequency	Percentage
Peristaltic movement of oesophagus	12	38.7
Content		
Small	13	52.0
Moderate	6	24.0
Huge	6	24.0
LES constriction		
Mild	7	25.0
Moderate	14	50.0
Severe	7	25.0

Barium swallow X-ray of oesophagus showed that 22.6% of the oesophagus was hugely dilated, 63.3% moderately dilated and 13.3% mildly dilated. About 42% patients exhibited bird-beak appearance and 58% narrowing of the lower end of oesophagus. Sixteen percent patients developed sigmoid-shaped oesophagus (Table-III).

Table-III: Findings of barium swallow X-ray of oesophagus

Findings	Frequency	Percentage
Oesophageal dilatation		
Mild	4	13.3
Moderate	19	63.3
Huge	7	22.6
Lower end of oesophagus		
Narrow	18	58.1
Bird breaking	13	41.9
Sigmoid shaped oesophagus	5	16.1

During pneumatic dilatation the median pressure in the balloon was 11.5 mm of water. The average time required to dilate the sphincter was 42.5 second, while the lowest and the highest time needed were 30 and 120 seconds respectively. Some patients required more than one sessions, and as such, the average number of sessions of pneumatic dilatation was 2 and the average years between the sessions was 5.

Immediate outcome of pneumatic dilatation shows that all the patients improved in terms of relief of dysphagia and discharged from hospital next day. In majority (96.4%) of the cases, mucosal tear was seen at endoscopy. 85% of the patients had minimal pain at the site of dilatation. However, 82.1% patients complained of chest pain. None of the patients complained of dysphagia or regurgitation of the undigested food (Figure-2).

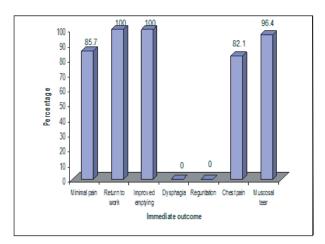


Figure- 2: Immediate outcome of pneumatic dilatation

Majority (82.1%) of the cases developed chest pain following pneumatic dilatation and 10.7% had bleeding from the site of dilatation but bleeding was not severe enough necessitating blood transfusion (Figure-3).

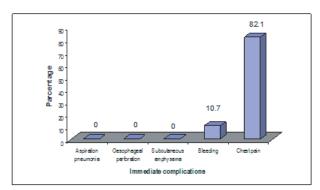


Figure- 2: Distribution of patients by immediate complications

The evaluation of the outcome of pneumatic dilatation after 4 weeks. General condition of all patients improved except one, although about 70% had heartburn, 7.7% had chest pain, another 7.7% had oesophageal ulcer and 3.4% persisted dysphagia (Figure-4).

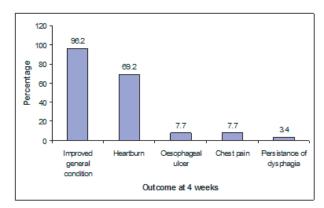


Figure-4: Distribution of patients by outcome at 4 weeks of evaluation

The weight of patients after 4 weeks of pneumatic dilatation increased significantly from their baseline status ( $45.5 \pm 9.4$  vs.  $50.2 \pm 9.0$ , p < 0.001). Comparing BMI before and after pneumatic dilatation also revealed that proportion of underweight patients reduced significantly from 57.7% before dilatation to 38.5% 4 weeks after dilatation (p = 0.036). (Table-IV).

Table-IV: Changes in weight and BMI after 4 weeks of dilatation

Variables	Before dilatation (n – 26)	4 weeks after dilatation (n = 26)
Weight (kg)#	45.5 ± 9.4	50.2 ± 9.0 *
BMI (kg/m2)	5	
Underweigh	t 15(57.7)	10(38.5)
Normal weig	ght 11(42.3)	16(61.5)

Figures in the parentheses correspond percentages.

- # Data were analysed using Wilcoxon Signed Rank Test and presented as mean  $\pm$  SD.
- ¶ Data were analysed using McNemar Chi-square Test.
- \* p-value < 0.001, \*\* p-value 0.036

### Discussion

The present study intended to find the outcome of pneumatic dilatation in patients of achalasia cardia and included a total of 31 patients. Of them 2 patients did not

complete the treatment and 3 patients dropped following pneumatic dilatation. Over 60% of the patients were younger (< 40 years old) with a mean age of 34 years (range 8 - 70 years) and male to female ratio roughly 1:1. More than 50% of the patients were underweight with respect to their BMI. Dysphagia for solids or liquids, bland regurgitation and weight loss were the universal complaints of the patients. Hiccup and symptoms of pneumonia were less commonly reported. Peristaltic movement of oesophagus was seen in 38% of the cases with moderate to huge content of undigested foods (48%) and moderate to severe constriction of LOS (75%). Barium swallows X-ray of oesophagus demonstrated moderate to hugely dilated oesophagus (86.7%) and either narrow (58.1%) or bird-beak (41.9%) appearance of lower end of oesophagus. Development of sigmoid oesophagus was substantially lower (16.1%).

Immediately after pneumatic dilatation all the patients got relief of dysphagia and were discharged from hospital next day. Mucosal tear was visible on endoscopic examination. Majority (96.2%) of patients at 4 weeks of evaluation experienced improved emptying of oesophagus, though heartburn and dysphagia were complained by 70% and 11.5% cases respectively. Four weeks after pneumatic dilatation, number underweight patients reduced to 38.5% from 57.7% at baseline. About 52% of the patients required 1 dilatation, 25.9% 2 dilatations and 22% 3 dilatations.

Ghoshal and associates conducted a retrospective study on 126 patients of achalasia cardia (mean age 36.5 ± 14.6 yrs, 76 male) to find the factors associated with nonresponse and recurrence after pneumatic dilatation (PD).<sup>13</sup> Symptoms were dysphagia (100%), chest pain (17%), regurgitation (48%), weight loss (26%), and pulmonary symptoms (18%); 5 of 126 (4%) had megaesophagus. The mean lower oesophageal sphincter (LOS) pressure was 38.7 ± 16.8 mmHg. Over 90% of patients responded to PD (71% to first session); 25 of these had recurrence of dysphagia after a median period 15 months. Post-PD chest pain requiring hospitalization occurred in 17%. Post-PD LOS pressure, which was assessed in 48 of 126 patients, had decreased by > 50% from baseline in 14 of 29 responders, none of 11 nonresponders and 5 of 8 relapsers. The median dysphagia-free duration was 60 months (95% CI = 54.7 - 65.3). In our study we did not measure lower oesophageal sphincter pressure. However, with respect to symptom relief and number of sessions required, the findings of the present study is quite consistent with those of Ghoshal et al (2004).<sup>13</sup>

In an updated review through 2009 of 1144 patients

across 24 studies with an average follow up of 37 months, Rigiflex pneumatic dilatation in a graded fashion gave good to excellent symptom relief in 74%, 86% and 90% treated with the 3.0, 3.5 and 4.0 cm balloon, respectively (Richer, 2008). Over a third of treated patients experienced symptom relapse after 4-6 years of follow-up.<sup>9</sup>

The risk factors for relapse after pneumatic dilatation are mainly young age (<40 years), male gender, single dilatation with a 3.0 cm balloon, post-treatment LOS pressure >10-15 mm Hg and poor esophageal emptying on an upright barium oesophagram (timed barium swallow). 6,9,12,13,14 Pneumatic dilatation is the most cost-effective treatment for achalasia cardia over a time period of 5 to 10 years. 15,16

Complications after pneumatic dilatation are reported in up to 33% of patients with most complications beingminor. In the present study as well we observed 82% patients to develop chest pain as immediate complications. Only 10% patients have had gastrointestinal bleeding but the bleeding was not too severe to require blood transfusion. However, Ghoshal (2004) reported a somewhat higher incidence of post PD chest pain (17%) requiring hospitalization (one of them had an esophageal perforation). <sup>13</sup>

There was no incidence of perforation after pneumatic dilatation. Severe complications like GORD are rare after pneumatic dilatation, but 15-35% of patients have heartburn responding to proton pump inhibitors.8 In our series patients who complained of heartburn 4 weeks after PD, 1 (3.4%) of them exhibited oesophageal ulcer on endoscopic examination. The patient responded well to proton pump inhibitors bearing consistency with findings of.<sup>8</sup>

From the findings of the present study and discussion thereof it can be concluded that all the patients following pneumatic dilatation relieved of obstruction in the lower oesophageal sphincter and improved emptying of oesophageal contents with relieved of dysphagia without major complications. Patients discharged from hospital next day and return to their usual work. Majority of the patients at 4 weeks follow up show improvement in oesophageal emptying, although some minor symptoms like heartburn and chestpain are complained. Pneumatic dilatation is a simple, safe and effective method for treating patients with achalasia cardia in Bangladeshi population.

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