

## Outcome of Pneumatic Balloon Dilatation in Achalasia Cardia

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### Abstract

#### Background:

Achalasia Cardia is a rare esophageal motility disorder. Among various treatment options, Pneumatic Dilatation (PD) is the most widely used and cost effective modality till date. This is the first observational study aiming to evaluate the short term response and complications of PD for Achalasia Cardia in Nepal.

#### Methods:

This prospective observational study was conducted between 28th Jan 2020 to 27th Jan 2021. It included 39 patients with Achalasia Cardia diagnosed by clinical presentation, esophagoscopy, barium esophagogram and high resolution manometry. Two patients of Type III achalasia were excluded from study. Thirty seven patients underwent pneumatic dilatation with 30 mm Rigiflex balloon (Boston Scientific, USA) for a duration of 1 minute. Response was assessed by Eckardts score at 3 and 6 months.

#### Result:

Among 39 cases (mean age= 39.03±15.017 years, 59% men), commonest was Type II Achalasia (71.8%) followed by Type I (23.1%) and Type III (5.1%). Dysphagia was present in all patients (100%), followed by weight loss (84.6%), regurgitation (79.5%) and chest pain (35.9%). Mean basal Eckardts score and Lower Esophageal Sphincter pressure of the study population was 7.81±1.24 and 24.40±6.83 respectively. Response to pneumatic dilatation was 89.2%. Eckardts score changed significantly from 7.81±1.24 to 1.03±1.82 at 6 months ( $p<0.001$ ). None of the patients had major complications. Younger age ( $23\pm6.377$  years) had poor response to treatment, while predilatation Lower Esophageal Sphincter pressure, gender and type of achalasia did not affect the treatment outcome.

#### Conclusion:

PD is safe and effective treatment modality for Achalasia. Younger patients have poor response to treatment with Pneumatic Dilatation.

### INTRODUCTION

Achalasia is a rare neurodegenerative esophageal motility disorder characterized by aperistalsis in the smooth muscle esophagus and failure of lower esophageal sphincter (LES) to relax during swallowing. Consequently these lead to symptoms of dysphagia, regurgitation, chest pain and weight loss.<sup>1</sup> Incidence of Achalasia varies between 0.03-3 per 100000 persons per year

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and prevalence of 10 per 100000 inhabitants.<sup>2,3</sup>

Diagnosis of achalasia is based on esophageal manometry, barium esophagogram and upper GI endoscopy. Three achalasia subtypes have been defined based on High Resolution Manometry (HRM). Pneumatic dilatation, Laparoscopic Heller Myotomy and Peroral Endoscopic Myotomy (POEM) are efficacious for subtypes I and II, whereas POEM does best for achalasia type III.<sup>4</sup> Though POEM is coming up as a good treatment option, it is still not practiced in resource limited country like Nepal. This study will bring forward the outcome of PD, the most practiced treatment modality, in our population.

## METHODS

This is a Prepost design study performed in the Department of Gastroenterology at National Academy of Medical Sciences, Bir Hospital, Kathmandu, Nepal from 28th Jan 2020 to 27th Jan 2021. Ethical approval was taken from institutional review board. Informed consent for participation was obtained from all participants.

Sample Size:

$$n = (Z\alpha + Z\beta)^2 \times \sigma^2 / d^2$$

•the size of the effect that is clinically worthwhile to detect has been set as  $(d) = 1$

•the probability of falsely rejecting a true null hypothesis ( $\alpha$ ) = 0.05,  $Z_\alpha = 1.96$

•the probability of failing to reject a false null hypothesis ( $\beta$ ) = 0.80,  $Z_\beta = 0.84$

the standard deviation (SD or  $\sigma$ ) = 1.75<sup>5</sup>

Hence,  $n = 24.01$

~25

The diagnosis of Achalasia was based on clinical symptoms, endoscopic findings, barium esophagograms and manometric studies. Adult patients aged 18-80 years with symptomatic Achalasia (Eckardt score  $\geq 3$ ) were enrolled. Achalasia patients with prior endoscopic or surgical treatment were excluded. HRM was performed using a low compliance, pneumohydraulic, water infusion system (Solar GI High-Resolution Manometry System) and 24 lumen, manometric catheter. Findings diagnostic of Achalasia on HRM were defined as absent peristalsis with impaired relaxation of the LES reflected by an integrated relaxation pressure (IRP) of at least 15 mm Hg.<sup>6</sup> Basal LES pressures were also recorded. Accordingly Achalasia was classified into three different types based on manometric findings.

Type I: 100% failed peristalsis, mean IRP > 15 mm Hg

Type II: No esophageal contraction and panesophageal pressurization with  $\geq 20\%$  of swallows;

mean IRP > 15 mm Hg

Type III: Premature contractions with  $\geq 20\%$  of swallows, mean IRP > 15 mm Hg

The Eckardt symptom score assesses the severity of achalasia symptoms by combining the sum of symptom frequency scores for dysphagia, regurgitation, and chest pain (range for each symptom, 0-3; 0 indicates absent; 1, occasionally; 2, daily; 3, at each meal) and a weight loss score (range, 0-3; 0 indicates no weight loss; 1, <5 kg of weight loss; 2, 5-10 kg of weight loss; 3, >10 kg of weight loss), resulting in a range of 0 (the lowest severity of symptoms) to 12 (the highest severity of symptoms).<sup>7</sup> This score is the most reliable and easiest score for assessing severity at bedside. Studies have shown that Type III Achalasia Cardia didn't respond satisfactorily to Pneumatic dilatation<sup>8,9</sup> so patients with Type III Achalasia were excluded from this study. Pseudoachalasia was ruled out by detailed upper gastrointestinal endoscopic examination in all patients.

All dilatations were performed under fluoroscopic guidance with a Rigidflex (Microvasive, Boston Scientific Corporation, Boston, MA, USA) achalasia balloon dilator by experienced gastroenterologists according to the ACG Clinical Guideline, 2014, 2018 ISDE achalasia guidelines and ASGE guidelines 2019.<sup>1,10,11</sup> A stiff guidewire was placed into the stomach through the endoscope. The balloon dilator was passed over the guidewire under endoscopic guidance and positioned at the ECJ under fluoroscopic control and inflated. The position of the catheter was adjusted so that the waist of the partly inflated balloon caused by the LES lay at the midpoint of the balloon. Full inflation was confirmed visually by the loss of the waist at the midpoint of the balloon. Since there has been no proper consensus about the duration of inflation, we inflated with 30mm balloon for a total of 60 seconds with 12 psi pressure. Post procedure gastroscopy was done for all patients. Tinge of fresh blood with easy give away were taken as positive finding. X-ray abdomen and chest were done for suspected patients of oesophageal rupture.

All patients were followed up regarding their symptoms at 1 month, 3 months & 6 months duration. Patients were contacted by OPD visit, telephone/ personal interview during their follow up. Therapeutic success of pneumatic balloon dilatation was defined as Eckardt score of 3 or less and nonresponders (failure) if score remained  $\geq 3$  postdilatation.<sup>12</sup>

Continuous measurements was presented as mean  $\pm$  standard deviation and categorical measurements as number (%). Continuous unpaired and paired data were analysed using

unpaired and paired t-tests, respectively. Categorical data were analysed using chi squared test. P values <0.05 were considered significant.

Result:

A total of 39 patients with Achalasia Cardia were evaluated. Mean age of the patients was 39.03±15.017 years. Total Males were 23(59%) and females were 16(41%). Male: Female ratio was 1.4:1. Dysphagia was present in all patients (100%), followed by weight loss (84.6%), regurgitation (79.5%) and chest pain (35.9%). Mean duration of symptoms was 35.18±24.442 months.

TABLE 1. CLINICAL PROFILE OF PATIENTS WITH VARIOUS TYPES OF ACHALASIA CARDIA

Total patients	39		
Age in years	Age in years		
Male/Female	23 (59%)/16 (41%)		
Duration of symptoms	35.18±24.44 months		
Baseline Eckardt's score	7.85±1.268		
Baseline IRP mm of Hg	24.91±7.03		
Baseline LES mm of Hg	37.87±10.01		
	Prevalence	Eckardt sub score (Mean±SD)	Duration in number of months (Mean±SD)
Symptoms	100%	2.9±0.30	43.59±36.01
Dysphagia	35.9%	0.67±0.955	28.44±16.16
Chest pain	79.5%	2.05±1.169	25.13±16.42
Regurgitation	84.6%	2.28±1.10	43.59±36.02
Weight loss			

Type I Achalasia was present in 9 (23.1%), Type II Achalasia was present in 28 (71.8%) and Type III Achalasia in 2 (5.1%) as shown in table 2.

TABLE 2. TYPES OF ACHALASIA CARDIA ACCORDING TO HRM

Achalasia Cardia Type	Frequency	%
Type I	9	23.1
Type II	28	71.8
Type III	2	5.1

Female were more in type I Achalasia (77.8%), but male dominated in Type II (71.4%). Mean basal Eckardt's score, LES pressure and IRP of the study population was 7.81±1.24, 37.19±9.81 and 24.40±6.83 respectively (similar in Type I and Type II) but slightly higher in type III (8.50±2.12, 34.50±7.03 and 50.50±2.121 respectively).

TABLE 3. COMPARISON OF BASELINE PARAMETERS IN VARIOUS TYPES OF ACHALASIA CARDIA

	Achalasia Type I	Achalasia Type II	Baseline of study patients (I & II)	Achalasia Type III	P value
Total Patients	9	28	37	2	
Age in years	35.44 ±9.72	40.46 ±16.76	39.24 ±15.38	39.03 ±15.02	0.646
Male	2	20	22	1	0.032
Female	7	8	15	1	
Duration of symptoms (months)	31.00 ±8.61	36.58 ±28.45	35.22 ±25.09	34.50 ±6.36	0.844
Dysphagia (Mean Eckardt sub-score +/- SD)	3.00 ±0.00	2.86 ±0.356	2.89 ±0.31	3.00 ±0.00	0.437
Chest pain (Mean Eckardt sub-score +/- SD)	0.78 ±1.20	0.57 ±0.88	0.62 ±0.79	1.50 ±0.707	0.393
Regurgitation (Mean Eckardt sub-score +/- SD)	1.67 ±1.41	2.25 ±1.04	2.11 ±0.84	1.00 ±1.41	0.185
Weight loss (Mean Eckardt sub-score +/- SD)	2.44 ±0.53	2.18 ±1.25	2.24 ±0.76	3.00 ±0.00	0.535
Baseline Eckardt's score	7.89 ±1.36	7.79 ±1.23	7.81 ±1.24	8.50 ±2.12	0.749
Baseline IRP mm of Hg	26.62 ±9.22	23.68 ±5.90	24.40 ±6.83	34.50 ±7.03	0.074
Baseline LES mm of Hg	38.667 ±8.573	36.718 ±10.274	37.19 ±9.81	50.50 ±2.121	0.165

Total of 37 patients of Type I and II Achalasia were assigned for Pneumatic dilatation. Four patients (10.8%) failed to respond to dilatation, two in Type I and two in Type II. Post dilatation Eckardt's

score changed significantly from 7.81±1.24 to 1.05±1.81 at 3 months and maintained on 1.03±1.82 at 6 months (P<0.001).

TABLE 4. ECKARDTS SCORE AT BASELINE, 3 AND 6 MONTHS POST TREATMENT

	Baseline Eckardt's score	Eckardt's score at 3 months	P value (comparing with baseline)	Eckardt's score at 6 months	P value (comparing with baseline)
Type I	7.89±1.364	1.78±2.728	<0.001	1.78±2.728	<0.001
Type II	7.79±1.228	0.82±1.389	<0.001	0.79±1.397	<0.001
Type I & II	7.81±1.24	1.05±1.81	<0.001	1.03±1.82	<0.001

Response to treatment was better in older patients than younger ones. The average age in responders was 41.21±15.012 years and nonresponders was 23±6.377 years. There was no association with response to treatment with sex, type of achalasia, duration of symptoms, basal IRP and basal LES pressure as shown in table 5. None of the patients had perforation or major bleeding during the procedure.

TABLE 5. COMPARISON OF VARIOUS PARAMETERS IN TYPE I AND II ACHALASIA IN RESPONDERS AND NONRESPONDERS

	Responders, n=33	Nonresponders, n=4	P value
Age in years	41.21±15.012	23±6.377	0.023
Male/Female	18/15 (54.54%/45.45%)	4/0 (100%/0%)	0.131
Duration of symptoms (months)	35.40±26.43	33.75±9.91	0.903
Basal IRP (mm of Hg)	24.49±7.08	23.60±4.79	0.809
Basal LES pressure (mm of Hg)	36.37±9.72	44.00±8.84	0.144
Type I vs Type II Achalasia	7/26	2/2	0.244

DISCUSSION

Achalasia cardia is the best characterised oesophageal motility disorder diagnosed by HRM. Achalasia occurs equally in males and females and can present at any ages, commonly between ages of 40-60 years.<sup>11,13</sup> In our study male slightly predominated over females and presented in 3rd to 5th decade. Manometrically,

achalasia cardia can be divided into three subtypes that aid treatment decision-making and hence have prognostic significance.<sup>4,6</sup> Type II achalasia is the most common subtype and has best response to PD while Type III is least common and has poor response to PD.<sup>8,14</sup> We found Type II Achalasia Cardia in 73.1% of patients which is in consistent with studies of Gupta et al and Shejal et al from India (75.8% and 80.5% respectively).<sup>15,16</sup> Pandolfino et al also found Type II as the commonest type.<sup>9</sup> Most common presenting symptom was dysphagia (100%) followed by weight loss, regurgitation and chest pain. Ghoshal et al also showed 100% of the patients presenting with dysphagia.<sup>17</sup> Mean age, presenting symptoms and their duration were similar in three types. Type I were predominantly female while type II and III were males. Baseline Eckardts score, IRP and LES pressure were all higher in patients with type III Achalasia. Pratap et al also found significantly higher basal LES pressure in Type III Achalasia (59.86 ±15.14, p=0.002).<sup>14</sup>

Treatment of Achalasia is directed towards symptomatic relief of dysphagia. Surgical risk factors of the patients and achalasia subtype plays a major role in choosing the best modality of treatment. In patients with low surgical risks, Type III Achalasia have best outcome with POEM, while others might benefit from pneumatic dilatation or Hellers myotomy. Short lasting botulinum toxin and pharmacotherapy (nitrates and CCB) are an option for high surgical risk candidates.<sup>13</sup> In the era of third space endoscopy, POEM has been showing good results with >90% success rate but with more adverse outcome of GERD, 23% vs 9% in POEM vs PD<sup>18,19</sup> Pneumatic dilatation is the cost effective, easily available and hence the most widely used procedure all over the world with success rates ranging from 54%–91%.<sup>11,16,17,20</sup> In our short term follow up of 6 months, we found response of 89.2% having Eckardts score of ≤3. The most feared complication following pneumatic dilatation is Esophageal perforation ranging from 2-4% in different series.<sup>11,12</sup> Ghoshal et al reported perforation of 0.8-3% in their studies.<sup>21</sup> Incidence of GERD post-PD is approximately 2-4%.<sup>5</sup> There were no major complications of perforation, bleeding or GERD in our study except for mild chest discomfort post procedure. Various parameters were compared with response to pneumatic dilatation, only age was found as the determining factor in this study. Younger age patients with average age of 23±6.377 years were poor responders. Duration of symptoms, type of Achalasia, sex, basal LES pressure and IRP had no roles in treatment outcome. Previous studies show mixed results for response prediction. Young age, high basal LES pressure, post dilatation LES pressure >10 mm Hg, Type III Achalasia Cardia, male sex and small size of balloon used are thought as predictors of poor response.<sup>7,17</sup>

Though POEM has shown better results than PD in recent RCT, this may have been biased by the use of smaller sized balloon and lesser duration of balloon inflation.<sup>18</sup> Also POEM is costly and requires lots of expertise. PD remains the most widely practiced technique in the resource limited settings and our study has

showed good success rate and no major complications with 30 mm balloon. Hence until the newer modalities are available in all parts of the world, PD can still be practiced with good safety and comparable efficacy.

We have various limitations of this study. Our small sample size diminished our statistical power. Follow up period was short, and thus chance of recurrence in long term couldn't not been assessed. We excluded patients with type III achalasia, so the effect of PD in these patients could not be evaluated.

#### CONCLUSION:

PD remains a safe and effective procedure for Type I and II Achalasia Cardia. Long term studies are needed for assessing its durability.

CONFLICT OF INTEREST: None

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