Original Article

Efficacy and Safety of Endoscopic-guided Balloon Dilatation without Fluoroscopy for the Treatment of Achalasia

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Background: Achalasia is a primary esophageal motor disorder of unknown etiology. One of the standard treatments is pneumatic balloon dilatation under fluoroscopic guidance. Endoscopic-guided balloon dilatation without fluoroscopy can also be performed, but the efficacy and associated safety issues remain unclear.

Objective: To assess efficacy and safety of endoscopic-guided balloon dilatation technique for achalasia treatment at Maharaj Nakorn Chiang Mai Hospital.

Materials and Methods: This study is a retrospective, descriptive study in achalasia patients who were initially diagnosed and treated with the endoscopic-guided balloon dilatation technique between January 2007 and December 2012. Achalasia symptoms before and after treatment were evaluated to assess the efficacy. Immediate complications and long term follow-up were used to assess safety of this method.

Results: Sixteen eligible achalasia patients who underwent the dilatation under endoscopic guidance were included in the analysis. There was a significant improvement in Eckardt score from 6.6$\pm$1.9 to 0.5$\pm$0.7 (p-value <0.001). All patients (100%) had improvement in dysphagia symptoms and gained weight after the dilatation procedure. No serious complications were observed.

Conclusion: Endoscopic guided pneumatic balloon dilatation as an initial treatment of achalasia is a safe technique and has a high level of efficacy.

Keywords: Achalasia, Endoscopy, Fluoroscopy, Pneumatic balloon dilatation

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Achalasia is a primary esophageal motor disorder of unknown etiology characterized by manometry showing impaired relaxation of the lower esophageal sphincter [LES] and simultaneous or failed esophageal peristalsis, resulting in patient complaints of dysphagia to solids and liquids, regurgitation, and occasional chest pain with or without weight loss[(1)]. Endoscopic findings of retained saliva and puckered gastroesophageal junction and/or a barium swallow showing dilated esophagus with bird-beak appearance are characteristics of this disease. To date, the pathogenesis of achalasia is still unclear, but the loss of the inhibitory ganglion cells and a decrease or absence of nitric oxide innervation in the myenteric plexus are agreed indications[(2)]. There is no curative

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treatment for this disease and the aim of the current treatment is to reduce LES pressure. Methods using pharmacologic, endoscopic or surgical therapy have been done to facilitate esophageal outflow and symptomatic relief to the patients. Currently the most effective treatment options for achalasia include pneumatic dilatation [PD], Heller myotomy and peroral endoscopic myotomy [POEM][3].

Standard pneumatic balloon dilation requires fluoroscopy guidance to assess the proper positioning of the balloon at the esophagogastric junction [EGJ], along with observation of the full dilatation indicated by a loss of balloon waist. This can be a problem in some hospitals that have limited access to fluoroscopy. PD under direct endoscopic guidance has been proposed with varied rates of success[4,5]. The efficacy and safety of this method remains unclear. Therefore, our study aims to report on the efficacy and safety of endoscopic guided PD.

Materials and Methods

Study design and study population

We conducted a retrospective descriptive study among achalasia patients in Maharaj Nakorn Chiang Mai Hospital between January 2007 and December 2012. The inclusion criteria for the patients were as follows: 1) aged 15 years or older; 2) a positive diagnosis of achalasia by esophago gastroduo denoscopy [EGD] and barium esophagography; 3) being initially treated with PD under endoscopic guidance and 4) have never received any other achalasia treatment. The patients were excluded from the analysis if there were insufficient data or if the patient had not returned for follow-up.

This study was approved by the Research Ethical Committeeof the Faculty of Medicine, Chiang Mai University.

Pneumatic balloon dilatation under endoscopic guidance

PD was performed after overnight fasting. The patients were sedated just before the procedure with intravenous midazolam and mepenidine. The patients lay in the left lateral position. First, an EGD was performed to locate the EGJ, then the distance from the incisor was taken. A guidewire was inserted into the duodenum to avoid dislocation. A 30-mm diameter Rigiflex™ balloon dilator (Boston Scientific Corp., Marlborough, MA) was placed in position via the guidewire, and the measurement were used to keep the middle part of the balloon at the EGJ. Dilatation was then performed under direct endoscopic view to confirm the correct positioning of the balloon. We inflated the balloon to the pressure of 8 to 18 Psi for 30 or 60 seconds. We used direct endoscopic observation to assure the final position and the full dilation of the balloon. After complete dilatation and balloon removal, EGD was performed again to check for any mucosal breaks. If there were no mucosal breaks observed a further session of dilatation using a larger balloon (35-mm diameter) would be arranged.

Data collection and study outcomes

The primary outcome of this study is the efficacy of treatment, evaluated using the method described by Eckardt[6]. This Eckardt score is the sum of the individual ratings for each symptom and sign, including severity of dysphagia, chest pain, regurgitation and recent weight loss. The score ranges from 0 to 3 for each symptom and the total score ranges from 0 to 12. A score of 0 to 2 after the treatment is defined as treatment success.

Data were collected from electronic medical records and telephone interviews (in cases that had incomplete symptoms evaluation). Demographic data of the patients, symptoms, duration of symptoms, technique of pneumatic balloon dilatation, outcome of treatment, rate of repeated dilatation and any complications were collected.

Statistical analysis

The descriptive data were presented in percentages, mean $\pm$ standard deviation [SD], and median (interquartile range, IQR) as appropriate. Comparisons of baseline and post-treatment symptoms were performed using a paired t-test. All statistical analyses were performed using Stata statistical software version 16.0 (Statacorp, College Station, TX). A p-value of <0.05 was used to indicate statistical significance in the two-sided test.

Results

Demographic and clinical data

Between January 2007 and December 2012, 26 achalasia patients were newly diagnosed, and underwent PD. The decision to perform PD either under fluoroscopic guidance or just with endoscopic guidance was at the discretion of the endoscopists. Seven patients underwent PD under fluoroscopic guidance. Nineteen patients underwent PD under endoscopic guidance and met the inclusion criteria and were enrolled onto the study. After the exclusion of 3

Table 1. Demographic and clinical data of patients

	Patients (n = 16)
Gender, n (%)	
Male	6 (37.5)
Female	10 (62.5)
Age (years), mean ± SD	49.0±16.4
Body weight (kg), mean ± SD	42.9±7.2
Duration of symptom (months), mean ± SD	13.8±18.6
Dysphagia, n (%)	
None	0
Occasional	0
Daily	1 (6.2)
Each after meal	15 (93.8)
Regurgitation, n (%)	
None	2 (12.5)
Occasional	5 (31.2)
Daily	5 (31.2)
Each after meal	4 (25)
Chest pain, n (%)	
None	11 (68.8)
Occasional	3 (18.7)
Daily	2 (12.5)
Each after meal	0
Recent weight loss, n (%)	
None	1 (6.25)
<5 kg	7 (43.7)
5 to 10 kg	4 (25)
>10 kg	4 (25)
Eckardt score	
Mean ± SD	6.6±1.9
Median (IQR)	6.5 (5.7 to 8)
Barium swallowing findings, n (%)	
Dilated esophagus	16 (100)
Aperistalsis	7 (43.7)
Bird's beak appearance	16 (100)
Endoscopic findings, n (%)	
Esophageal dilatation	16 (100)
Food retention in esophagus	12 (75)
LES spasm	16 (100)

IQR = interquartile range; LES = lower esophageal sphincter; SD = standard deviation

patients due to incomplete data and were not contactable, 16 patients were included in the analysis. The demographic and clinical data of the patients are shown in Table 1. Ten patients (62.5%) were female and the mean age was 49.0±16.4 years. Mean duration of symptoms was 13.8±18.6 months. All patients had clinical dysphagia and weight loss. Mean baseline Eckardt score was 6.6±1.9.

Pneumatic dilatation under endoscopic guidance technique

All patients underwent dilatation with a Rigiflex™ 30-mm diameter balloon. Mucosal breaks were observed in all cases; therefore, no patient needed an additional session of dilatation with a larger balloon. The range of inflation pressure was 8 to 17 Psi with a median pressure of 10 Psi (IQR 8 to 12). The balloon was inflated for 60 seconds in 14 patients (87.5%), and 30 seconds in 2 patients (12.5%).

Efficacy of endoscopic guided PD treatment

The mean clinical score, Eckardt score and score changes at baseline and after dilatation are shown in Table 2. All patients had improvement of dysphagia symptoms. Twelve patients (75%) had a complete response and four patients (25%) experienced decreased severity of dysphagia. Among patients who had baseline regurgitation (n = 14), complete response and improvement with occasional regurgitation were observed in 13 (92.8%) and in 1 patient (7.2%), respectively. Among patients who had baseline chest pain (n = 5), complete response and improvement with occasional chest pain were observed in 3 (60%) and in 1 patient (20%), respectively. One patient had persistent occasional chest pain after dilatation (20%). All patients gained weight after the dilatation.

Eckardt scores were significantly improved after the dilatation, the mean scores at baseline and after treatment were 6.6±1.9 and 0.5±0.7 (p-value <0.001). All patients reported a score of less than 3 after the dilatation.

Four patients had symptom relapse and required repeated dilatation. The interval between the first dilatation and second dilatation were 1, 2, 3, 16 months in these 4 patients. To date, repeated dilatations have been carried out and no surgical treatment has been necessary.

Safety of pneumatic balloon dilatation

No serious complications were observed in this study. There was only one patient who developed clinical heartburn after the dilatation. Her symptoms improved with medical treatment.

Discussion

Previous studies using PD with fluoroscopic guidance in cases of achalasia reported a high success rate of 71% to 91.3% after the first PD[7,8]. The outcomes

Table 2. Symptom score at baseline and after pneumatic balloon dilatation

Symptoms	Baseline	After dilatation	Mean changes	*p*-value
Dysphagia	2.75±0.58	0.25±0.44	-2.50±0.63	<0.001*
Regurgitation	1.68±1.01	0.06±0.25	-1.62±1.08	<0.001*
Chest pain	0.44±0.72	0.18±0.40	-0.25±0.68	0.164
Weight loss	1.68±0.94	0	-1.68±0.94	<0.001*
Eckardt score	6.56±1.96	0.50±0.73	-6.06±2.24	<0.001*

Data presented in mean ± standard deviation. * Statistical significance $p<0.05$

and safety of PD for achalasia treatment without fluoroscopic guidance was first reported by Lambroza, et al. That study included 27 achalasia patients. The inflation pressures and duration of dilatation were similar to our study. In that study, a 30 mm diameter balloon was used in 67% of cases. A success rate of 78% was observed after a single dilatation session[4]. Another study by Chuah et al, which included 33 achalasia patients, reported 90.9% good to excellent results at 1 year after PD. All patients in this study underwent dilatation using a 30-mm diameter balloon[5]. In our study all patients reported improvement of dysphagia and had a complete response, evaluated using an Eckardt score of less than 3, after the first dilatation. Compared with the standard fluoroscopic guided PD and endoscopic guided PD procedures reported in other studies, our study demonstrated comparable and satisfactory success rates of 81.3% at one year after the dilatation had been performed.

The rate of perforation after PD under fluoroscopic guidance was 0.8% to 1.3%[7,8]. Our study showed a good safety profile of this technique with no perforation observed after the procedure. As the diameter of the balloon used for dilatation was 30 mm in all cases in our study, this may imply that using small size balloon initially is very safe. We cannot evaluate the safety profile of larger balloon, as we limited the initial size of the balloon, and no patient required the larger one.

Our study had several limitations. First, a manometric diagnosis and a post-dilatation evaluation of the lower esophageal pressure response were not performed, as these facilities are not available in our institution. Hence, there is no data regarding the type of achalasia. Second, there were a relatively small number of patients in our study. Finally, response of treatment was evaluated by a review of electronic medical records and telephone interview so there might be some errors from recall bias.

Conclusion

The present study demonstrated a high level of efficacy and safety of endoscopic-guided PD as an initial therapy for achalasia patients. This technique can therefore be recommended an alternative method to fluoroscopic-guided PD in a fluoroscopy equipment-limited setting.

What is already known on this topic?

Achalasia is a primary esophageal motor disorder of unknown etiology and no curative treatment. Pneumatic balloon dilatation under fluoroscopic guidance is one of the standard treatments.

What this study adds?

Endoscopic guided pneumatic balloon dilatation can be an alternative technique to the standard fluoroscopic guided balloon dilatation. This technique provided high efficacy and safety, outcomes being similar to those reported in what is accepted as the standard management under fluoroscopic guidance.

Potential conflicts of interest

None.

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