Original Article

Factors determining successful outcome following pneumatic balloon dilation in achalasia cardia

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Background: Pneumatic balloon dilation is a popular method of treating patients with achalasia cardia. It may be useful to know the factors that predict response to this treatment. **Aim:** To determine predictors of outcome following pneumatic balloon dilation in patients with achalasia cardia. **Methods:** Records of 62 patients who had undergone pneumatic dilation using *Rigiflex* balloon dilators (Boston Scientific, Boston, MA, USA) were reviewed. Follow-up data were available for 52 patients. Data from patients with and without improvement in symptoms were compared. **Results:** Of the 52 patients (age mean 44 [range 11-68] years; 27 male; median symptom duration 20 [4-90] months], 42 (81%) patients had response in symptoms after balloon dilatation. On univariate analysis, the responders more often had age >40 years (26/42 [62%] versus 1/10 [10%], p=0.003), and less often had lower esophageal sphincter pressure >50 mmHg (8/10 [80%] versus 10/42 [24%], p=0.0007) and mid-esophageal body hypocontraction (7/10 [70%] versus 12/24 [29%] p=0.01) than the non-responders. On multivariate analysis only age ≤40 years (p=0.02) was associated with poor outcome. **Conclusion:** Younger age may predict non-response to balloon dilation using *Rigiflex* balloon dilators in patients with achalasia cardia. [*Indian J Gastroenterol* 2005;24:243-245]

Primary achalasia cardia is characterized by aperistalsis of the esophageal body and incomplete or absent relaxation of the lower esophageal sphincter (LES) in response to swallowing, leading to impaired propulsion of food bolus.[1] Treatment of this condition is aimed at reducing resistance to flow at the level of the esophagogastric junction. This can be achieved using one of several methods, viz., pharmacological agents like nitrates and calcium-channel blockers,[1] endoscopic injection of botulinum toxin,[2] endoscopic pneumatic dilation, or surgical myotomy. The balloon dilators are designed to distend the LES to a diameter of 30-40 mm, thereby disrupting the sphinteric 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.

We retrospectively analyzed data of our patients with achalasia cardia to determine predictors of successful outcome following pneumatic dilation using *Rigiflex* dilators.

Methods

During January 2000 to November 2004, 62 patients with primary achalasia underwent pneumatic balloon dilation using *Rigiflex* balloon dilator. Diagnosis in these patients was based on clinical, radiological, endoscopic and manometry data. Esophageal manometry (Sandhill Scientific, Highlands Ranch, CO, USA) was performed using a solid-state pressure catheter and station pull-through technique. Diagnosis of classic achalasia or vigorous achalasia (amplitude of esophageal contractions >40 mmHg) was established using standard manometric criteria.[4] Amplitude less than 30 mmHg in absence of simultaneous aperistaltic wave in mid-esophageal body was considered mid-esophageal hypocontraction.[5]

As per our center's policy, all patients initially underwent graded dilation (30 mm first dilation followed by 35 mm second dilation after 4 weeks, followed by 40 mm third dilation in case of non response) using a *Rigiflex* balloon, under conscious sedation. Patients were followed up once in 3 months if dilation was successful. Data on balloon size, number of sessions of dilation, clinical response and major complications (such as perforation) and minor complications (chest pain and gastroesophageal reflux) were retrieved from medical records (n=30) or obtained by telephonic interview at the time of analysis (n=22).

Total symptoms score was calculated as suggested by Eckardt[6] (dysphagia, chest pain, regurgitation and weight loss, each graded as 0 to 3 points, with total symptom score from 0 to 12). Balloon dilation was considered successful if total symptom score was 0-1 at the last follow-up visit or telephonic contact, irrespective of number of dilation

sessions. Failure of balloon dilation was defined as symptom score exceeding 1 even if only one dilation session had been done.

Data from patients with previous Heller's myotomy (n=4) and those who were lost during follow up (n=6) were excluded. Thus, data for 52 patients were analyzed. Univariate analysis was performed by *chi*-squared test and *p* values below 0.05 were considered significant. Multivariate logistic regression analysis was performed by using SPSS software (Chicago, IL, USA; Windows software version 10.1).

Results

In the 52 patients analyzed (age mean 44 years, range 11-68; 27 male), the median duration of symptoms was 20 (range 4-90) months. Dysphagia to solids and liquids was the presenting symptom in 50 (96%) patients, regurgitation in 32 (62%), retrosternal pain in 10 (19%), and weight loss in 5 (10%) patients. Eighty-five sessions of balloon dilation were performed, and the median follow-up duration was 36 (4-54) months.

Balloon dilation was successful in 42 (81%) patients (responders); of these, 26, 12 and 4 patients had undergone one, two and three sessions of balloon dilation each, respectively (Fig). In 10 (19%) patients, dilation failed to relieve symptoms. Of these, two and three patients received one and two sessions of dilation each, respectively, and refused further dilation. The remaining five patients had no response despite three dilation sessions each. Of these 10 non-responders, 7 underwent Heller's myotomy and three declined further treatment. Mean number of sessions of dilation in responders and non-responders was 1.5 and 2.3, respectively.

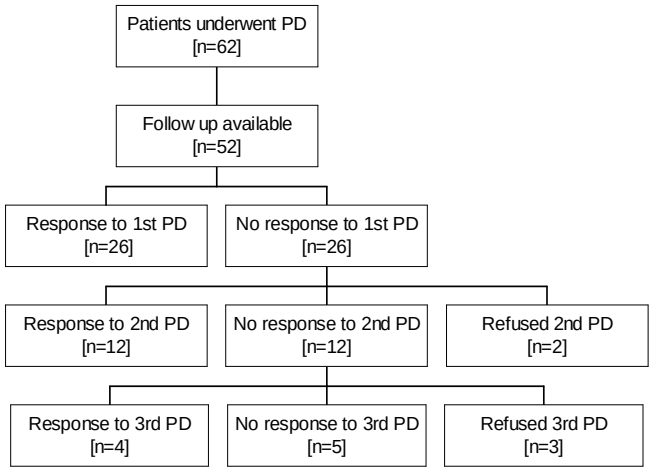

Fig: Flowchart of results of pneumatic dilataon (PD) in patients with achalasia cardia

Table: Comparison of patients with success and failure to respond to balloon dilation

	Responders (n=42)	Non-responders (n=10)
Age >40 years	26 (62)	1 (10)**
Gender (female)	22 (52)	3 (30)
LES pressure >50 mmHg	10 (24)	8 (80)***
Mid-esophageal hypocontractions	12 (29)	7 (70)*
Duration of illness >12 mo	23 (55)	5 (50)

p *<0.01, **<0.005, ***<0.001. Data in parentheses are percentages

Five (9.6%) patients had prolonged post-dilation chest pain; none had esophageal perforation.

Univariate analysis showed non-responders were more often younger than 40 years of age, had LES pressure >50 mmHg and mid-esophageal hypocontractions (Table). Female patients had similar response rate as males (22/42 [52%] versus 3/10 [30%], p=0.08). Multivariate analysis showed age ≤40 years (p=0.02) was associated with poor response, while LES pressure >50 mmHg (p=0.06), mid-esophageal hypocontractions (p=0.53) and duration of symptoms >12 months (p=0.92) were not different between the groups.

Discussion

Rigiflex pneumatic balloon dilation is considered the most effective non-surgical treatment for achalasia.[3] In eight prospective studies that included 280 patients who underwent *Rigiflex* balloon dilation using 30, 35 or 40 mm dilators,[7-14] median success rate after 16-month follow-up was 81%. However, it is difficult to ascertain whether in these studies increasing dilator diameters were used or not. We found a similar success rate after a median follow up of 36 months.

Complications after pneumatic dilation have been reported in up to 33% of patients, with most being minor.[14] The overall perforation rate using *Rigiflex* balloon dilator has been less than 2.5%.[3] We did not encounter esophageal perforation after any of the 85 dilation sessions in 52 patients. Kadakia *et al*[7] also reported similar results after 78 procedures. Birgisson *et al*[16] observed a higher perforation rate with the use of 35-mm balloon as the initial dilator (10.6%) than that with 30-mm balloon (2.8%).

In the present study, age ≤40 years was a predictor of poor response to pneumatic dilation; others too have shown similar results.[17,18] Female patients had similar response rate as male patients (52% vs 30%; p=ns). Ghoshal *et al*[19] found a poor

response to balloon dilation among males. Though previous studies[19,20,21] had shown that pretreatment LES pressure did not influence response rate, we found that LES pressure >50 mmHg was associated with poor response on univariate analysis. Mid-esophageal hypocontractions were associated with poor response on univariate analysis; this finding has not been reported previously. Both these parameters were insignificant on multivariate alysis. Duration of illness did not influence response to pneumatic dilation, as has also been reported by others.[17,18,19]

Our study had a limitation. Post-dilation manometry was not performed in our patients; in previous studies[19,20] post-dilation LES pressure ≤10 mmHg was shown to predict response of symptoms to pneumatic dilation.

In conclusion, younger age may predict non-response to balloon dilation using *Rigiflex* balloon dilators in patients with achalasia cardia.

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