

LONG TERM RESULTS OF SINGLE SESSION OF PNEUMATIC DILATATION WITH 30 MM BALLOON FOR ACHALASIA CARDIA

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ABSTRACT

Objective: To evaluate the results of single session of endoscopic balloon dilation with 30mm pneumatic balloon for achalasia, over a prolonged (≥ 12 months) observation period.

Methodology: This prospective interventional study was carried out in a Gastro-enterology center in private set up in Akbar Medical Center, Ramdaas, Peshawar, Khyber Pakhtunkhwa, Pakistan from January 2010 to December 2015.

Results: Out of 31 patients, males were 18(58%) and females were 13(42%), with mean age of 38 ± 13 years. Stable clinical remission (SCR) was achieved in 25 (80.6%) patients over a mean follow up of 27 ± 10 months after single session of dilation.

Conclusion: Pneumatic dilation was successful in a significantly high number of achalasia patients. The response was durable and the procedure was safe with minimal complications.

Key Words: Achalasia, Pneumatic dilation, Pneumatic achalasia balloon

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INTRODUCTION

Achalasia cardia is a primary esophageal motility disorder characterized by loss of esophageal peristalsis and impaired or absent relaxation of lower esophageal sphincter in response to swallow^{1,2}. Its prevalence is about 10/100,000 of general population³. Achalasia patients typically present with progressive dysphagia (both for solids and liquids), regurgitation of undigested foods and chest pain⁴. As Achalasia is untreatable, the aim of achalasia management is to provide symptomatic improvement by decreasing lower esophageal sphincter pressure⁵. Different options for achalasia management are pharmacologic therapy i.e. calcium channel blocker or nitrates, surgical therapy i.e. Heller myotomy or laparoscopic myotomy, endoscopic therapy i.e. pneumatic dilation, per oral endoscopic myotomy (POEM), injection of botulinum toxin and metal or plastic stent^{6,7}.

Pharmacologic therapy may be prescribed in mild cases of achalasia, but their modest efficacy along with significant side effects limit their use in clinical practice⁸. Surgery is an effective therapeutic option but it is

invasive and carries significant mortality and morbidity compared with endoscopic management⁹. POEM is an emerging endoscopic therapeutic modality but it is technically challenging and long term follow up studies are not available¹⁰. Gastro-enterologists recommend pneumatic dilatation as initial therapeutic step because it is cost effective and yields high success rate i.e. 70% to 90%. Little data is available regarding long term efficacy of single pneumatic dilation¹¹.

The aim of our study was to evaluate the results of single session of endoscopic balloon dilation with 30mm pneumatic balloon for achalasia, over a prolonged (≥ 12 months) observation period. The results of this study will provide a basis for single session of pneumatic dilation with small pneumatic balloon protocol thus reducing the cost and complications resulting from multiple sessions using larger pneumatic balloons.

METHODOLOGY

We conducted this prospective interventional study in a Gastroenterology clinic in private set up in Akbar Medical Center, Ramdaas, Peshawar, Khyber Pakhtunkhwa, Pakistan from January 2010 to December

2015. We included patients who met the diagnostic criteria of achalasia based on typical radiologic and endoscopic findings and Eckardt score ≥ 4 applying consecutive non-probability sampling. Patients who previously had Heller myotomy or refused pneumatic dilation were excluded from the study. Achalasia was diagnosed on the basis of history of dysphagia, barium study (showing distal narrowing of the esophagus, bird beak deformity and variable degrees of dilation of the proximal esophagus) and exclusion of mechanical obstruction on endoscopy. Esophageal manometry is not available in Peshawar, KP. Patients' symptoms were assessed and Eckardt score was calculated for all patients. Pneumatic dilation was done by single trained gastro-enterologist with 30mm achalasia balloon (Rigiflex, Boston Scientific Corporation, Boston, MA, USA) under direct endoscopic vision, after taking informed consent. Patients were observed for six hours and then sent home if no adverse event was noticed during observation period. Patients were followed up yearly or when symptoms re-emerged. Those patients who did not turn up for follow up visit, they were interviewed on phone. Our primary end point stable clinical remission was defined as Eckardt score ≤ 3 twelve months after the procedure. Patients' data was entered in a predesigned proforma and analyzed by us-

ing SPSS version 17. Categorical data was expressed in percentages and numerical data was expressed as mean \pm standard deviation.

RESULTS

Total 38 patients underwent pneumatic dilation in our study period. Seven patients lost to follow up. Demographic features of patients are given in table 1. SCR was achieved in 80.6% patients over a mean follow up of 27 ± 10 months after single session of dilation. Six (19.4%) patients did not respond to single session and they were dilated with larger balloon and four patients responded while two (6%) patients did not respond. One of the non-responders was referred to cardiothoracic unit where he underwent Heller myotomy and the other patient underwent per oral endoscopic myotomy (POEM) in Pakistan Society of Gastroenterology annual conference 2015 by foreign faculty (risk, benefits and alternate options were explained to the patient and patient's consent was taken before referring him for the procedure). Thus Pneumatic dilation was successful in 29(94%) patients. None of the patients had major immediate complication and all were sent home six hours after the procedure (table 2).

Table 1: Baseline characteristics of the patients

Male	18 (58%)
Female	13 (42%)
Age	38 ± 13.9 Years
Eckardt Score	7.22 ± 1.2
Duration of Follow up	27.22 ± 10.9 Months

Table 2: Complications of pneumatic dilatation

Complications	Frequency
Gastro-esophageal Reflux Disease	10 (32%)
Perforation	0
Esophageal Hematoma	0

Annexure 1: Clinical scoring system for achalasia (Eckardt score)

Score	Dysphagia	Regurgitation	Retrosternal Pain	Weight loss (kg)
0	None	None	None	None
1	Occasional	Occasional	Occasional	<5
2	Daily	Daily	Daily	5-10
3	Each Meal	Each Meal	Each Meal	>10

DISCUSSION

The success rate of pneumatic dilatation reported in various studies ranges from 58% to 93%^{6,12-14}. A long term follow up study reported more than 80% success rate in 1st year and a overall cumulative success rates at 5, 10 and 15 years of 78%, 61% and 58.3% respectively. However that study did not set criteria for achalasia balloon size and number of dilation sessions¹³. A study conducted in Karachi reported that 22 (69%) patients responded to single session of pneumatic dilation¹¹. A study conducted in Islamabad reported that 92% patients had improvement in symptoms after single session of balloon dilation over a follow up period of 6-23 months¹⁴. A study conducted by Sajida et al⁶ in Karachi, reported success rate of 80% with single session of pneumatic dilation but 30 mm achalasia balloon was used in only 60% of their patients for initial dilation. A meta-analysis involving 21 studies reported 66% success rate of a single pneumatic dilation session. As the length of follow-up continued, the efficacy diminished at 2, 3 and 5 year intervals determined to be 60, 53 and 50% respectively. These studies did not set criteria for size of pneumatic balloon and different diameter balloons were used in same study¹⁵. In our study success rate of single pneumatic dilation with 30 mm pneumatic balloon was 80.6% and overall success rate of 94%, which is consistent with available literature. In our study six (19.4%) patients had second session with 35 mm balloon and four patients responded; however the number of patients with multiple dilations was too small to make inferences on this basis. Sajida et al⁶ reported 20% of the patients required second session with larger balloon. Another study from Karachi reported that 30% of the patients had second session of dilation¹¹. In our study 2 (6%) patients underwent myotomy. Two studies from Karachi reported 10% and 19% referral for surgery^{6,11}. One of our non-responder patient was 13 year old, which is consistent with the fact that younger patients respond poorly to pneumatic dilation. It has been reported in several studies that younger age is associated with poor response to pneumatic dilation¹⁶. Thick lower esophageal sphincter in younger patients is suggested as cause of this poor response¹⁷. Kadakia et al¹⁸ recommended myotomy as initial treatment for achalasia for patients less than eighteen years of age.

The perforation rate with pneumatic dilatation is reported as 0-6.6%. The safest approach is to start with pneumatic dilation with a 30 mm balloon and then progress to 35 mm and 40 mm if needed²⁰. Meta-analysis of 25 studies reported 2% perforation rate following pneumatic dilation¹⁴. In our study none of our patients had perforation. The smallest size balloon used for dilation for our patients can be possible explanation for 0% perforation rate in our study. The most common late complication of achalasia balloon dilatation is gas-

tro-esophageal reflux disease (GERD). 15-35% of the patients present with GERD after pneumatic balloon dilation⁶. In our study 32% of patients had GERD, all these patients responded to life style modification, proton pump inhibitors and prokinetics.

LIMITATIONS

Potential shortcomings of our study included small sample size and single center study design.

CONCLUSION

Pneumatic dilation was successful in a significantly high number of achalasia patients. The response was durable and the procedure was safe with minimal complications.

REFERENCES

1. Bravi I, Nicita MT, Duca P, Grigolon A, Cantù P, Caparelli C, Penagini R. A pneumatic dilation strategy in achalasia: prospective outcome and effects on oesophageal motor function in the long term. *Aliment Pharmacol Ther* 2010; 31: 658-65.
2. Eckardt VF, Gockel I, Bernhard G. Pneumatic dilation for achalasia: late results of a prospective follow up investigation. *Gut* 2004; 53:629-33.
3. Park W, Vaezi MF. Etiology and pathogenesis of achalasia: the current understanding. *Am J Gastroenterol* 2005; 100:1404-14.
4. Dughera L, Chiaverina M, Cacciotella L, Cisarò F. Management of achalasia. *Clin Exp Gastroenterol* 2011; 4:33-41.
5. Lopushinsky SR, Urbach DR. Pneumatic dilatation and surgical myotomy for achalasia. *J Am Med Assoc* 2006; 18: 2227-33.
6. Qureshi S, Ghazanfar S, Tasleem S, Taj A. Pneumatic Balloon Dilation of Achalasia Cardia. *J Surg Pak* 2015; 20:1-4.
7. Boeckxstaens GE, Annese V, des Varannes SB, Chaussade S, Costantini M, Cuttitta A et al. Pneumatic dilation versus laparoscopic Heller's myotomy for idiopathic achalasia. *N Engl J Med* 2011; 364:1807-16.
8. Patti MG, Fisichella PM, Perretta S, Galvani C, Gorodner MV, Robinson T, et al. Impact of minimally invasive surgery on the treatment of esophageal achalasia: a decade of change. *J Am Coll Surg* 2003; 196:698-703.
9. Winter H, Shukla R, Elshaer M, Riaz AA. Current Management of Achalasia-A Review. *Br J Med Pract* 2015; 8:a810.
10. Dunaway PM, Wong RK. Achalasia Current Treatment Options. *Gastroenterol* 2001; 4:89-100.
11. Ahmed WU, Qureshi H, Arif A, Mahr M. Achalasia in a gastroenterology unit of Karachi. *J Pak Med Assoc* 2008; 58:661-4.

12. Katsinelos P, Kountouras J, Paroutoglou G. Long-term results of pneumatic dilation for achalasia: a 15 years' experience. *W J Gastroenterol* 2005; 36: 5701-5.
13. O'Neill OM, Johnston BT, Coleman HG. Achalasia: A review of clinical diagnosis, epidemiology, treatment and outcomes. *World J Gastroenterol* 2013; 21:5806-12
14. Hyder Q, Rashid R, Hadi SF, Qamar T. Endoscopic Assessment of effacement of balloon waist during pneumatic dilatation of primary achalasia cardia under topical anesthesia. *Pak J Med Sci* 2008; 24:491-6.
15. Katzka DA, Castell DO. Review article: an analysis of the efficacy, perforation rates and methods used in pneumatic dilation for achalasia. *Aliment Pharmacol Ther* 2011; 34: 832-39.
16. Hulselmans M, Vanuytsel T, Degreef T, Sifrim D, Coosemans W, Lerut T et al. Long-term outcome of pneumatic dilation in the treatment of achalasia. *Clin Gastroenterol Hepatol* 2010; 8:30-5.
17. Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol* 2013; 108:1238-49.
18. Kadakia SC, Wong RK. Pneumatic balloon dilation for esophageal achalasia. *Gastrointest Endosc Clin N Am* 2001; 11:325-46.

CONTRIBUTORS

MKH and MAK conceived the idea, planned the study, and drafted the manuscript. SB Designed the study and did statistical analysis. ANB helped drafted the manuscript. AK and HK did critical reviews. AGK supervised the study and critically revised the manuscript. All authors contributed significantly to the submitted manuscript.