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GRADED PNEUMATIC DILATATION WITHOUT FLUOROSCOPY IN THE TREATMENT OF ESOPHAGEAL ACHALASIA

J. MIKAELI, R. MALEKZADEH, M. KHATIBIAN, R. ANSARI, H. VAHEDI AND H. SOLIMANI

From the Department of Gastroenterology and Digestive Disease Research Center, Shariati Hospital, Tehran University of Medical Sciences, Tehran, I.R. Iran.

ABSTRACT

Between 1993-1996 seventy-three consecutive patients (33 M, 40 F, mean age 35.4) with newly diagnosed achalasia underwent one or more pneumatic dilatations with the Rigiflex balloon using a protocol of graded dilatation with a fixed inflation pressure of 10 psi and constant duration of 30 seconds for all patients without using fluoroscopy. Using Vantrappen's classification for assessment of response, excellent or good results were considered as cure and fair or poor results as failure. Duration of symptoms and the amount of weight loss before dilatation averaged 5.2 years and 10 kg, respectively. In 62 patients one, in 5 patients two, and in 4 patients three dilatations were performed. Dilatation failed in one patient because of previous surgery and was followed by perforation in one patient (1.4%) and bleeding in another patient (1.4%). Follow up period averaged 20 months (range 6-38 months) with a cure rate of 90% (57 excellent, 9 good) and failure rate of 6.8% (3 fair, 2 poor). We conclude that graded pneumatic dilatation without fluoroscopy is a safe and very effective treatment for achalasia with 90% of patients having a sustained response lasting at least for an average of 20 months.

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Keywords: Achalasia, pneumatic dilatation, fluoroscopy, esophageal perforation.

INTRODUCTION

The cause of primary esophageal achalasia is unknown and the optimal management of this disease also remains controversial.[1] Drugs, pneumatic dilatation (PD), botulinum toxin injection (BTI) and surgery are the options available. Nifedipine,[2] the most effective drug in the treatment of achalasia, is helpful only in short term,[3,4] and while BTI seems to be an effective and safe technique, the symptoms tend to recur in most patients within 12 months of therapy.[5,6] Surgical myotomy reduces LES pressure more dependably than does pneumatic dilatation, accounting for its greater efficacy. The initial response to surgical myotomy is more than 90% at 1 year. Surgical myotomy, although very successful,[8] is more invasive, costly, and its long term outcome is not certain,[9] and reoperation or post-surgical pneumatic dilatation is rendered more difficult. The most significant complication of surgical myotomy is gastroesophageal reflux. Pneumatic dilatation is usually the first therapy that is offered to most patients with achalasia by gastroenterologists. Since Russel's first description of pneumatic dilatation in 1898, the instruments and techniques of dilatation have changed significantly and

Address for correspondence:
Professor R. Malekzadeh, M.D.,
Shariati Hospital,
Kargar Shomali Ave.,
Tehran 14114, I.R. Iran.

the present guidelines for esophageal dilatation by the American Society for Gastrointestinal Endoscopy [11] (ASGE) recommend use of fluoroscopic monitoring during dilatation. We describe our experience with graded pneumatic dilatation without fluoroscopic control and provide further evidence for the efficacy and safety of this technique.

METHODS

From October 1993 to November 1996, 73 consecutive patients with achalasia were recruited for this study. The diagnosis of achalasia was based on typical clinical, radiographic and endoscopic findings in all patients. Before dilatation, gastroscopy was performed to exclude esophageal tumor, ulcer or epiphrenic diverticulum. Rigiflex polyethylene dilators (Microvasive, Natick, MA) 30, 35 or 40 mm in diameter and 10 cm long, mounted on a one meter, 7 Fr catheter were used which slide over a metal guidewire. The 35 mm balloon was used for initial dilatation except for those with previous surgery, sigmoid esophagus, or hiatal hernia where we started with a 30 mm balloon, and the failure cases were subsequently dilated with 35 or 40 mm dilators. After sedation with intravenous diazepam and meperidine and use of Xylocaine spray, esophagogastroduodenoscopy was performed and a guidewire was placed in the stomach and the gastroscope was removed. A Rigiflex balloon of 35 mm (in 65 cases) or 30 mm size, increasing up to 40 mm in subsequent dilatations was passed over the guidewire inside the stomach, and the endoscope was inserted again. Under direct endoscopic view and without fluoroscopic guidance, the balloon was withdrawn from the stomach and placed with its midpoint across the lower esophageal sphincter (LES). Determination of the balloon midpoint was easy by estimation of the length of balloon above the LES using the double markings present on its shaft. Following appropriate positioning, the balloon was inflated up to a pressure of 10 psi for 30 seconds in all patients. The dilatation was repeated in case of a suboptimal result (absence of mucosal tear or hemorrhage at GE junction). After the procedure all patients were observed for 5 to 7 hours in the endoscopy department for signs or symptoms of perforation and if any clinical evidence of perforation appeared the patients underwent emergency esophagography. Symptom assessment was done at the onset and during the study using a standardized questionnaire and the outcome was determined using Vantrappen's clinical classification.[12,13] Excellent or good results were considered as cure and fair or poor results as failure (Table I). Four weeks after successful dilatation all patients were examined and were told to refer when they ever became symptomatic. Asymptomatic patients were assessed every 4 months till the end of the study.

Table I. Clinical outcome after dilatation.

Clinical outcome evaluation	
Excellent	Asymptomatic no dysphagia
Good	Minimal symptoms occasional transient dysphagia
Fair	Moderate symptoms once a week dysphagia
Poor	Symptomatic with daily regular dysphagia

RESULTS

Seventy-three patients (40 females and 33 males) ranging in age from 10-74 years (mean = 36 yr), under-went 85 balloon dilatations (1.2 dilations per patient). In all patients except one with previous surgery, balloon placement and the dilatation procedure was successful. In 63 patients one, in 5 patients two and in 4 patients three dilatations were performed. Clinical data at the time of presentation and clinical outcome at the end of the study are shown in Table II and III, respectively.

The mean duration of symptoms before dilatation was 5.2 years (range 3 months to 21 years), and the amount of weight loss (in those patients with this sign) averaged 10 kg. Five patients had a history of previous surgery (myotomy) for achalasia before attempted dilatation. In one patient the procedure failed but in the other 4 patients dilation was successful (good or excellent result). The mean follow up period was 20 months (6 - 38 months). Two patients who failed to respond to dilatation underwent myotomy (2.7% operation rate); one of them responded very well to surgery but the other responded only partially. In 3 patients severe persistent pain developed after dilatation and one of them subsequently was found to have a perforation (1.4%) while the other two responded to analgesics and were discharged the next day in good state. One patient (1.4%) developed bleeding who received 500 cc of whole blood and was discharged the next day also in good state. At the end of the follow up period 90% of patients remained in remission (57 excellent and 9 good results) and 5 patients (6.8%) remained symptomatic with a less than 1.4% (one patient) perforation rate (Table III).

DISCUSSION

During the past 20 years several studies have emphasized the need for fluoroscopic guidance during Maloney esophageal dilatation for benign esophageal stricture [18-21] or balloon dilatation for achalasia [22] and the present ASGE

Table II. Clinical data on presentation.

Data	No.	%
No. of patients	73	100%
Dysphagia for solids	73	100%
Dysphagia for liquids	68	93%
Active regurgitation	58	79%
Passive regurgitation	44	60%
Weight loss	54	74%
Chest pain	45	62%
Heartburn	15	20%

Table III. Clinical outcome after dilatation.

Group	No.	%
Excellent	57	78%
Good	9	12%
Fair	3	4.1%
Poor	2	2.7%
Failed	1	1.4%
Perforation	1	1.4%

guidelines recommend the mandatory use of fluoroscopic monitoring during dilatation.

With the development of non-expandable, low compliance balloons for pneumatic dilatation, treatment of achalasia has become more simplified and the complication rate has decreased. Nevertheless, the recommended mandatory use of fluoroscopy is time consuming and costly, with the hazard of exposure to radiation for both the patient and physician. There is also no consensus as to optimal balloon diameter inflation pressure, duration, or number of inflations. Our study, although non-randomized, is a well-designed prospective study in an attempt to answer the above questions.

Despite the recent introduction of BTI as a safe and effective short term therapy for achalasia, the recurrence of symptoms in most patients in long term, the uncertainty regarding the safety of repeated BTI treatments and the higher cost of such therapy would make pneumatic dilatation the first line of therapy, at least in developing countries where facilities are limited.

Our results clearly demonstrate that graded pneumatic dilatation of esophageal achalasia can be accomplished safely and easily with a success rate of near 90% without using fluoroscopy. This study also confirms the results obtained by other investigators regarding safety, simplicity and high success rate of low compliance Rigiflex balloon dilators in the treatment of achalasia.[15,16]

We also showed that using a fixed 10 psi pressure for a fixed period of 30 seconds in all patients while increasing the diameter of the balloon as guided by pre-dilatation circumstances and post-dilatation clinical evaluation would give a 90% success rate for a period of at least 20 months.

The results obtained in this study of a 90% cure rate is comparable to studies of fluoroscopically - guided balloon dilatations by others, [13,26] with a lower complication rate. Five of our patients had previous surgery that failed to cure their disease and these patients underwent successful dilatation with satisfactory results. Our technique could well be used for patients with previous myotomy. As described above PD can be done in the outpatient setting with low cost and good patient satisfaction.

This study confirmed the results obtained by other investigators as to the safety and efficacy of pneumatic dilation without fluoroscopy[23-25] and emphasizes the role of graded pneumatic dilation as reported earlier by Vantrappen[13] and recently by others[23] and suggests a fixed dilatation pressure of 10 psi with a fixed 30-second duration of dilation without added risk of complications.

In conclusion, PD without fluoroscopy as described above seems to be the best treatment to be offered as the first step to most patients with achalasia. Only in a selected group of patients, such as those with comorbid conditions, sigmoid esophagus and epiphrenic diverticulum should BTI be considered first. In patients with poor relief after BTI or surgery, PD could also be offered with good results.

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