Rigiflex pneumatic dilation of achalasia without fluoroscopy: a novel office procedure

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Background: Pneumatic balloon dilation is the most effective nonsurgical treatment to relieve functional obstruction of the gastroesophageal junction in achalasia. Since its inception, the conventional technique has been performed under direct fluoroscopic control with or without a guidewire. To overcome the impediments of the conventional technique and radiation exposure, we have devised a novel technique of achalasia dilation without fluoroscopy. The aim of the study was to evaluate the efficacy, the safety, and the outcome of the new method.

Methods: Fifty-six patients (34 men, 22 women) (mean age 32 years) with achalasia cardia were subjected, over a span of 2 years, to dilation with a Gruntzig-type (Rigiflex balloon) pneumatic dilator with the new technique. Clinical response and complications were assessed.

Observations: Excellent improvement in dysphagia, pain, and regurgitation was observed in 92.9%, 89.3%, and 89.3% patients at 24 hours, 6 weeks, and 6 months after dilation, respectively. The mean time to maneuver the Rigiflex balloon to the antrum was 30 seconds. The procedure was successfully done in all patients, and there were no procedural failures. The mean time of the procedure was 8 minutes. There were no complications or mortality during the study.

Conclusions: Achalasia dilation with this new technique has excellent results and is devoid of the side effects of radiation. It can be done as an office procedure, without the need of a fluoroscopy setup.

The primary aim in treatment of achalasia is to relieve functional obstruction at the gastroesophageal junction. Pneumatic dilation has been a standard, safe, and widely accepted treatment modality for endoscopic management of achalasia.[1,2]

Since its inception, the conventional technique has been performed under direct fluoroscopic control, with or without the use of a guidewire.[2] The procedure involves precise coordination between the therapeutic endoscopist and the radiologist.

The endoscopic staff, the radiologist, and the patient are at risk of radiation exposure. The usual exposure time sometimes may be prolonged because of multiple factors, such as an uncooperative patient, a difficult anatomy, difficulty in positioning the center of the balloon at the gastroesophageal junction, and, finally, difficulty in visualizing that an appropriate and sufficient span is created at the center of the balloon during inflation. The entire procedure is done under fluoroscopic control, but it is difficult to determine the mucosal injury during the dilation. A repeat endoscopy becomes essential to assess the mucosal tear.

The procedure, which uses a guidewire, can be cumbersome, because 16% of patients of achalasia have a sigmoid tortuous esophagus and the gastroesophageal junction is immensely taut. A thin, flaccid guidewire compounds the problem, because it is difficult to maneuver it across the gastroesophageal junction.[1]

In about 15% patients, the endoscopist is unable to advance the balloon to the point where the entire balloon segment is clearly within the stomach. Such a situation usually is confronted in cases of a cascade stomach or a horizontally oriented stomach. In addition to the aforementioned structural anomalies, an unyielding cardiospasm is another obstacle. Thus, in these subsets of patients, there is a disproportionately high incidence of therapeutic failure. Investigators in the past have proposed various methods of dilator introduction; but, these techniques were cumbersome and time consuming and required special wires and equipment.[1]

Techniques of achalasia dilation without fluoroscopic assistance have been described in the past; however, these techniques had various shortcomings.[3,4]

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To obviate these technical and procedural impediments, we have devised a new technique for the introduction of the Microvasive Rigiflex Achalasia Balloon Dilator (ABD) (Boston Scientific Corp, Boston, Mass), which is done under direct endoscopic visualization, without a guidewire and fluoroscopic assistance.

The aims of the study were to evaluate the technical feasibility, clinical efficacy, outcome, and complications of a new method of achalasia dilation.

Capsule Summary

What is already known on this topic

- Pneumatic balloon dilation under combined endoscopic and fluoroscopic guidance is the most effective and long-lasting nonsurgical treatment for esophageal achalasia.

What this study adds to our knowledge

- In a single-center, feasibility study, Rigiflex balloon dilation was successfully and safely performed without fluoroscopy and under retroflexed endoscopic visualization.

PATIENTS AND METHODS

The study was conducted in the Department of Gastroenterology, SMS Medical College, Jaipur, India, from January 1, 2001 to December 31, 2003. Consecutive patients of probable achalasia cardia were prospectively enrolled during the study period. An entire cohort of patients had not received any form of treatment prior to the study. A detailed analysis of the symptoms was recorded. The diagnosis of achalasia was based on clinical, endoscopic, and barium swallow studies. None of the patients had a hiatus hernia or a diverticulum. Manometric studies and endoscopic US were not done for establishing the diagnosis of achalasia. A routine upper-GI endoscopy was done to exclude the presence of secondary causes of achalasia. All patients were evaluated to exclude all possible causes of esophageal dysmotility, namely GERD, collagen vascular diseases, and diabetes mellitus.

The patients were evaluated for dysphagia and respiratory symptoms to generate a symptom score. A symptom score was established before and 24 hours after dilation, and during follow-up at 6 weeks and at 6 months. The symptom score for dysphagia, regurgitation, chest pain, and heartburn was calculated by multiplying the frequency of a symptom (0, never; 1, less than once a month; 2, approximately once a month; 3, approximately once a week; 4, several times a week; 5, daily) by the severity (1, mild; 2, moderate; 3, severe; 4, very severe) as proposed by Kim et al.[5] The highest attainable score for each symptom was 20. An excellent, a good, and a poor response to balloon dilation was considered to be achieved when the symptom score decreased by 75% or more, 50% or more, and less than 50%, respectively.

The ethical committee of our hospital approved the study. Informed consent was acquired before pneumatic dilation.

All pneumatic dilations were performed with a Microvasive Rigiflex ABD dilator, 35-mm diameter, 20 psi. The inflation pressure used was 10 psi, with obliteration of a balloon waist maintained for 2 minutes.

Dilation procedure

The procedure was performed after an overnight fast. In patients with dilated, tortuous, redundant, and sigmoid esophagus, a nasogastric tube was positioned in the esophagus, and suction of the contents was done. The procedure was done with the patient under conscious sedation with 0.05 mg/kg of intravenous midazolam, as a slow intravenous injection, with heart rate and oxygen saturation monitoring. A polypectomy snare was passed through the biopsy channel. When the snare came out at the distal end of the endoscope, its loop was opened. The tip of the balloon was grasped in the loop of the snare in such a manner that only a small portion of the tip of balloon was in front of the endoscope. The deflated part of the balloon was wrapped around the endoscope. Topical anesthesia was achieved with Xylocaine spray (AstraZeneca Pharma India Ltd, Bangalore, India) on the posterior pharyngeal wall. A 2% Xylocaine jelly (AstraZeneca Pharma India Ltd) was applied on the endoscope and the balloon.

The endoscope then was passed in tandem with the balloon through the gastroesophageal junction (Fig. 1A). Direct visualization facilitated the maneuvering of the assembly across the gastroesophageal junction in cases of a dilated, sigmoid, or tortuous esophagus.

The dilator was carried up to the antrum, along with the endoscope. The snare loop then was opened, and the pneumatic dilator tip was released. The snare then was withdrawn out of the endoscope. The endoscope then was retroverted to visualize the gastroesophageal junction (Fig. 1B).

The endoscopic assistant then was asked to pull the Rigiflex dilator up to the point where the central white marking on the balloon shaft was positioned at the gastroesophageal junction (Fig. 1C). After positioning of the balloon, air was inflated at 10 psi and maintained for 2 minutes (Fig. 1D). The assistant was asked to maintain tension to prevent the migration of the balloon into the stomach during inflation. During the entire procedure, the endoscopist kept the endoscope in retroflexion and constantly observed that the central white marking on the balloon shaft was maintained at the gastroesophageal junction (Fig. 2). Then, the balloon was deflated, and the dilator was slowly withdrawn, keeping the scope in situ.

During the initial few sessions of dilation, fluoroscopic screening of the procedure was done to ascertain and

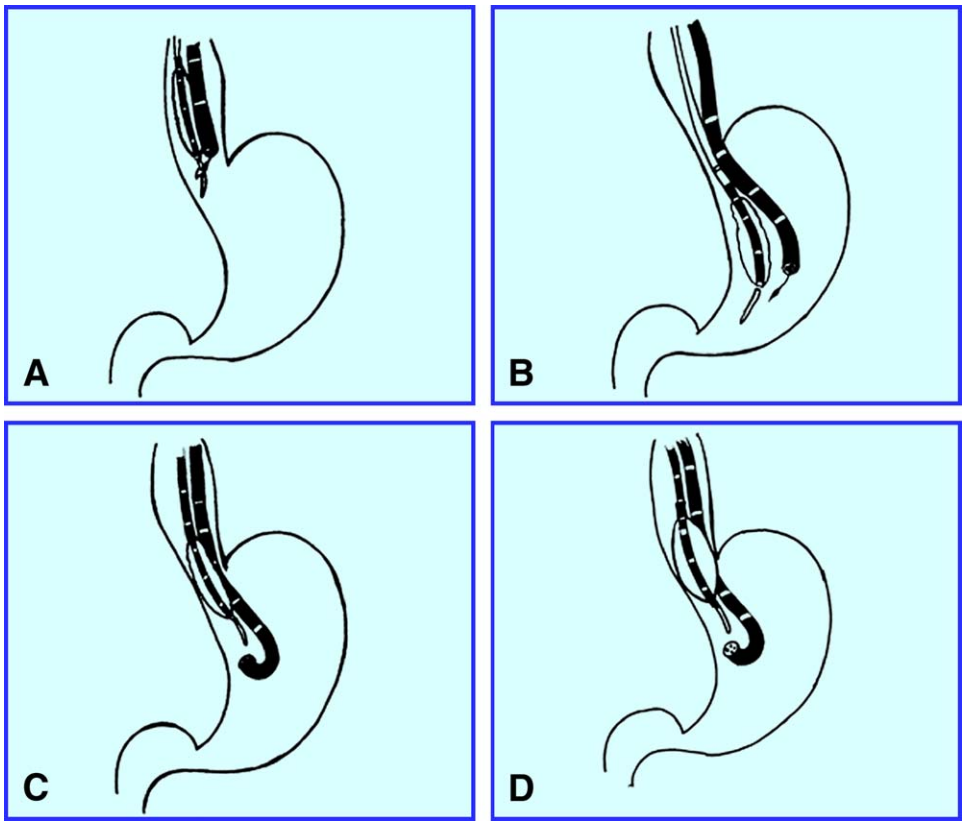

Figure 1. A, Pneumatic dilator introduced in tandem with endoscope across gastroesophageal junction. **B,** Releasing the dilator from the snare. **C,** Positioning of the center of the balloon across the gastroesophageal junction. **D,** Inflation of the balloon with air after proper positioning.

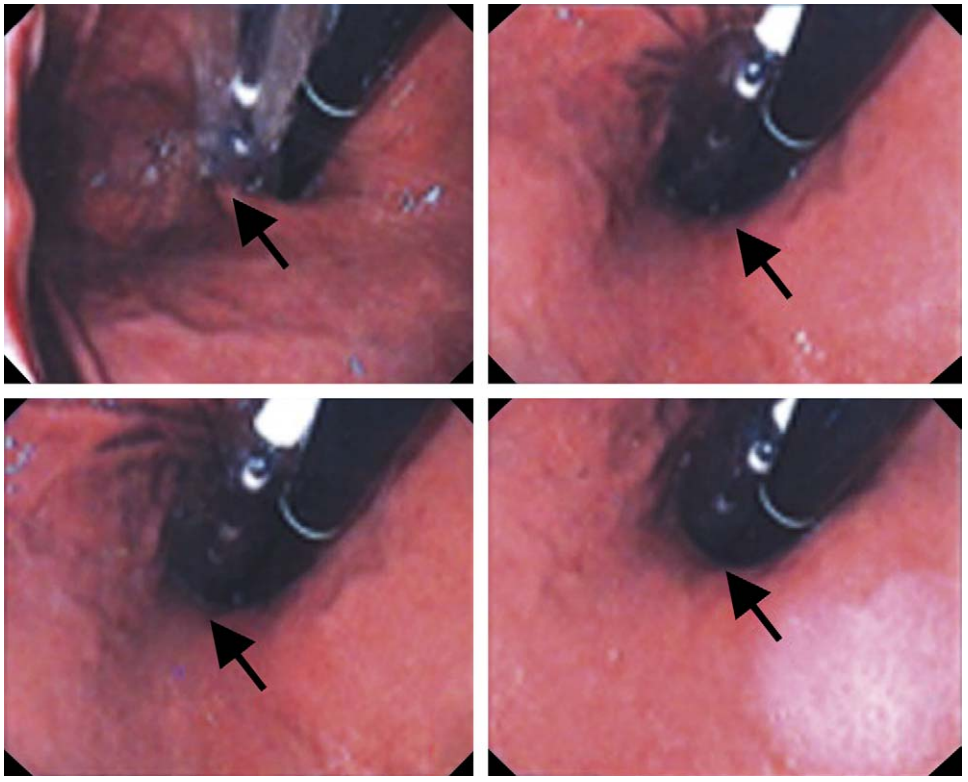

Figure 2. Endoscopic photographs of the procedure; inflated balloon (*black arrows*).

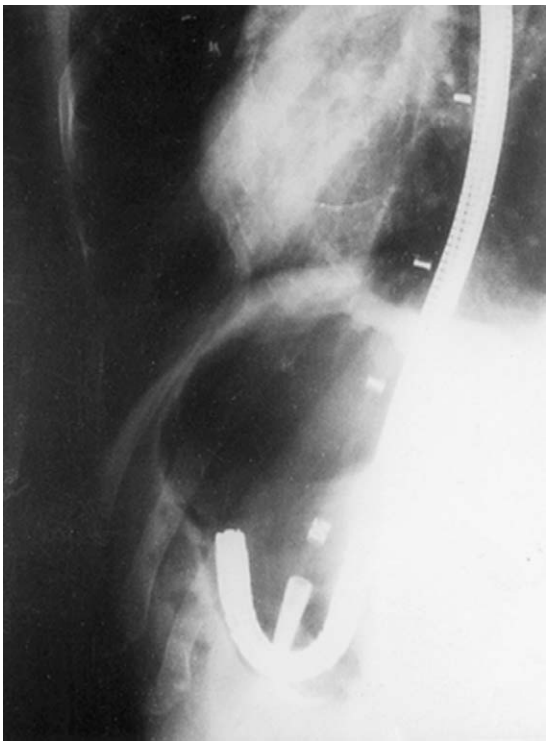

Figure 3. Radiograph showing the position of the center of the balloon at the gastroesophageal junction.

document the position of the dilator at the gastroesophageal junction (Fig. 3). Then, all procedures were performed without fluoroscopic control.

The endoscope then was slowly withdrawn across the gastroesophageal junction to assess for mucosal tears, submucosal hemorrhage, and perforation.

The patients were kept on intravenous fluids and antibiotics for the next 24 hours. A postprocedural chest radiograph was done to rule out esophageal perforation. Postdilation emptying of solids and liquids was assessed by taking a careful history, followed by a timed barium emptying study.

RESULTS

A total of 56 patients were registered in the study. There were 34 (60.7%) men and 22 (39.3%) women, with a median age of 32 years (range 19-64 years). The patients were subjected to achalasia dilation after preprocedural assessment.

The mean time to maneuver the Rigiflex balloon up to the antrum of the stomach was 30 seconds. The procedure was successfully done in all the patients, and there were no procedural failures. The mean time of the procedure was 8 minutes, and patient compliance and cooperation was excellent with the patient under conscious sedation.

Patients were evaluated at 24 hours after accomplishment of the procedure, and at 6 weeks and 6 months after dilation. Fifty-two patients (92.9%) had an excellent response, two patients (3.6%) had a good response, while only two patients (3.6%) had a poor response. Esophageal emptying of both solids and liquids improved significantly after the first session of dilation in 92.9% patients. The two patients with a poor response were subjected to a repeat session of dilation, with a good response after the second session. A follow-up at 6 weeks showed the maintenance of an excellent response in 50 (89.3%) patients, while two patients, who had a good response immediately after the first session, showed deterioration of symptoms and then exhibited a poor response. These two patients were subjected to repeat dilation, and, when followed at 6 months, were seen to maintain a good response. The remaining 50 patients (89.3%) continued to have an excellent response. Six patients had a good response at 6 months.

None of the patients required surgical cardiomyotomy, and there were no procedure-related complications and mortality. Postdilation gastroesophageal reflux-like symptoms occurred in only one patient.

DISCUSSION

Pneumatic balloon dilation is the most effective nonsurgical treatment modality to relieve dysphagia in patients with achalasia.[5]

However, the technique of pneumatic dilation has not yet been standardized. Therapeutic endoscopists continue to use various available dilators in accordance with their training, experience, and preferences.

In the conventional fluoroscopy-guided technique, difficulties are encountered when maneuvering the balloon over the wire in a large, tortuous, sigmoid esophagus and in gastric anomalies such as a cascade stomach or a horizontally oriented stomach. The present technique has an advantage over the other techniques. The balloon in this procedure is carried in tandem with the endoscope, through the esophagus and the gastroesophageal junction to the antrum under direct visualization. This helps in the successful positioning of the balloon at the gastroesophageal junction.

A technique of inserting an achalasia balloon previously described by investigators is time consuming and involves the usage of wires and other equipment.[1] However, the present technique is more versatile and quicker, and only requires a loop snare.

The technique of achalasia dilation, described in the past without fluoroscopy, involved the visualization of gastroesophageal junction when using a pediatric endoscope placed in the esophagus. However, visualization is hampered in such a situation.[3] Moreover, assessment of the lower esophageal sphincter in the presence of an epiphrenic diverticulum and a hiatus hernia is difficult when

using this technique. A retroflexed endoscopic view is superior in appreciating the center of the balloon at the gastroesophageal junction, because the central white marking is constantly under direct visualization. Thus, it helps in assessing mucosal injury and in monitoring dilation.

The positioning of the balloon may take longer when using a conventional method, thus increasing the radiation exposure. On the contrary, the present technique can be performed in the endoscopy suite without fluoroscopic facilities. The assistance of a radiologist is not required, which further reduces the overall cost of the procedure.

Commercially, two types of pneumatic dilators are available: a high-compliance balloon and a low-compliance balloon. High-compliance balloons are the Rider-Moeller device and the Brown–McHardy dilator (Narco Scientifics, Piling Division, Fort Washington, Pa), while low-compliance balloons are the Gruntzig-type dilator and the Witzel dilator (Wimed, Berlin, Germany). We used a low-compliance balloon (Gruntzig-type, Rigiflex dilator), because it has various theoretical advantages over a high-compliance balloon.[6]

A similar system is an exchangeable low-compliance balloon, the Witzel balloon, which is mounted over the endoscope, and dilation is done in a retroverted direct endoscopic visualization.[7] However, our system has the ease of quick deployment, because the balloon is passed in tandem with the endoscope and mounting over the endoscope is avoided; hence, this leads to a remarkable reduction in the procedure time. Moreover, the Witzel dilator is available only in the 4-cm size, thus, nonavailability of graded dilation jeopardizes the safety of the procedure and predisposes to increased chances of complications.[7]

Borotto et al[8] observed twice as many perforations with the Witzel balloon as with the Rigiflex balloon. The retroflexed position maintained during dilation with the Witzel balloon required persistent inflation, which increases the intragastric pressure. This sustained inflation might help to increase the pressure of the esophageal contractions and, thus, explain the larger number of perforations with the Witzel balloon.[8] However, we did not encounter a complication of esophageal or gastric perforation because of inflation of the stomach, and the air might have escaped through the inner tube of the Rigiflex balloon, which was kept open during the procedure.

A 0% perforation rate reported by previous investigators also was documented in our study.[9] There were no procedural failures or trauma to the oropharynx during any session. There was no instrumental damage to the endoscope or the Rigiflex dilator.

We achieved an excellent response to dilation in 89.3% patients, which is comparable with other investigators, who have reported overall success rates ranging from 70% to 100%.[2,5,6,9-12]

We believe that the low-compliance balloon dilation is safer and more convenient, with ideal, endoscopic retrograde control of the balloon position. This technique facilitates ideal positioning of the balloon at the gastroesophageal junction and assessment of mucosal tear during and after the procedure. It is comfortable to both patient and operator because of a single introduction of the endoscope, and safe because of a low-compliance system, thus preventing complications, e.g., esophageal perforation. Finally, the hazards related to radiation are avoided.

CONCLUSIONS

We conclude that this innovation in the technique is efficacious and safe. It is ''operator-patient–endoscope'' friendly and is cost effective. It, moreover, can be performed at centers where fluoroscopic facilities are not available.

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