World Journal of Gastroenterology

Online Submissions: http://www.wjgnet.com/1007-9327office
wjg@wjgnet.com
doi:10.3748/wjg.v16.i4.411

World J Gastroenterol 2010 January 28; 16(4): 411-417
ISSN 1007-9327 (print)

EDITORIAL

Endoscope-guided pneumatic dilation for treatment of esophageal achalasia

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Received: October 19, 2009 Revised: December 14, 2009
Accepted: December 21, 2009
Published online: January 28, 2010

Abstract

Pneumatic dilation (PD) is considered to be the first line nonsurgical therapy for achalasia. The principle of the procedure is to weaken the lower esophageal sphincter by tearing its muscle fibers by generating radial force. The endoscope-guided procedure is done without fluoroscopic control. Clinicians usually use a low-compliance balloon such as Rigiflex dilator to perform endoscope-guided PD for the treatment of esophageal achalasia. It has the advantage of determining mucosal injury during the dilation process, so that a repeat endoscopy is not needed to assess the mucosal tearing. Previous studies have shown that endoscope-guided PD is an efficient and safe nonsurgical therapy with results that compare well with other treatment modalities. Although the results may be promising, long-term follow-up is required in the near future.

Key words: Esophagoscopy; Dilatation; Esophageal achalasia

Peer reviewers: Kyoichi Adachi, MD, Department of Gastroenterology and Hepatology, Shimane University, School of Medicine Shimane, 89-1 Enya-cho, Izumo-shi Shimane 693-8501, Japan; Fabio Pace, Professor, Division of Gastroenterology, "L. Sacco" University Hospital, University of Milan, Via G. B. Grassi, 74, Milano 20157, Italy

Chuah SK, Wu KL, Hu TH, Tai WC, Changchien CS. Endoscope-guided pneumatic dilation for treatment of esophageal achalasia. *World J Gastroenterol* 2010; 16(4): 411-417 Available from: URL: http://www.wjgnet.com/1007-9327/full/v16/i4/411.htm DOI: http://dx.doi.org/10.3748/wjg.v16.i4.411

INTRODUCTION

Achalasia occurs at all ages; the mean occurrence is in middle age and affects both sexes and all races equally. The diagnosis is made by examinations such as barium esophagography, and esophageal manometry and endoscopy, after it has been distinguished from secondary achalasia caused by malignancy[1-5]. The truth we are facing in dealing with esophageal achalasia is that there is so far no cure for the disease. There are currently three main treatment modalities: pneumatic dilation (PD), surgery and botulinum toxin (BT) injection therapy. All therapeutic approaches are to loosen the lower esophageal sphincter (LES), because LES dysfunction leads to obstruction of the esophagus[6-20]. The goals are to relieve symptoms, improve esophageal emptying and avoid megaesophagus[21]. Traditional smooth muscle relaxants in the form of nitrates and calcium channel antagonists play little role. Besides, there are many intolerable side effects such as headaches, hypotension, and eventual tachyphylaxis[22,23].

No doubt, PD is considered to be the first line nonsurgical therapy for achalasia. The principle of the procedure is to weaken the LES by tearing its muscle fibers by generating radial force. For many decades, there have been many reports about long-term efficacy of

PD in the treatment of achalasia under the guidance of fluoroscopy[16-20]. However, some factors may hinder the practice of PD by some gastroenterologists. Some may have fear of the misplaced risk of perforation, and the overall decreased immediate morbidity from laparoscopic myotomy. It is the responsibility of gastroenterologists to continue the tradition of PD as a generally available technique, or otherwise, myotomy may become the routine available therapy for achalasia.

Another reason may be concern about expose to the X-rays during the procedure under fluoroscopic guidance[24-26]. Some of the highest doses to both patients and medical workers only arise from some other interventional radiology procedures[12,26]. Potential high doses during interventional procedures have been reached despite the procedure being carried out on equipment that normally has effective local shielding, so that the dose outside the lead coat is relatively low during fluoroscopy[12,27]. However, fluoroscopic-guided PD requires positioning of the balloon, which may need longer time, thus increasing the radiation exposure. Besides, the entire endoscope-guided PD procedure is done under direct visual control. It is easy to determine the mucosal injury during the dilation. Unlike fluoroscopic-guided PD, a repeat endoscopy to assess the mucosal tearing is not needed. The issue of the endoscope-guided PD for the treatment of esophageal achalasia is reviewed and discussed in this paper.

ENDOSCOPE-GUIDED PD

Levine *et al*[25] first proposed a safe and convenient PD technique under endoscopic guidance without the use of fluoroscopy. Since then, this technique has been used by many physicians[11,12,23,28-35]. There are many types of pneumatic dilators commercially available. The high-compliance balloons are the Rider-Moeller device and the Brown-McHardy dilator (Narco Scientifics, Piling Division, Fort Washington, PA, USA), Witzel dilator (ABS, par d' Activite Saint Michel, France) while the low-compliance balloons such as Gruntzig-type dilator (Rigiflex dilator; Microvasive, Watertown, MA, USA). Clinicians usually prefer using the low-compliance balloon (Gruntzig-type, Rigiflex dilator), because it has various theoretical advantages over a high-compliance balloon[34]. Rigiflex dilator is designed so that it can be inflated to a desired maximum diameter. Further inflation can only result in the increase of the pressure but not the diameter[35]. Therefore, the wall tension is increased maximally at the stenotic zone. In contrast, an inflated high-compliance balloon may lead to an increase in the esophageal wall tension more proximal to the stenotic zone more than the stenotic zone itself, which may lead to perforation, by the Laplace law[36-38]. Such speculation is supported theoretically by the fact that the most common site of esophageal perforation is proximal to the cardia on the left lateral side of the esophagus in clinical practice[34,35].

TECHNIQUE OF ENDOSCOPE-GUIDED PD

There is so far no clear consensus on the optimal method for performing PD with regard to balloon diameter, and the amount and rate of inflation pressure. It has been shown that the risk of perforation increases with the size of the balloon[39]. Mikaeli's[39] and Karamanolis' groups[14] have reported that graded pneumatic balloon dilatation with a 30-mm diameter and slower rate of balloon inflation is an effective and safe initial method of therapy for achalasia. According to our experience, we recommend that a 3.0-cm dilator with a smaller average inflation pressure of 10-12 psi is sufficient to attain satisfactory clinical remission, at least for oriental populations[14].

Endoscope-guided PD is carried out by choosing a desirable diameter of balloon dilator, under conscious sedation, with informed consent after an overnight fast. Nowadays, the low-compliance Rigiflex dilator is preferred by most doctors. The endoscope is inserted down to the duodenum (Figure 1A). A guide-wire is placed into the duodenum under endoscopic guidance and then the endoscope is removed (Figure 1B). A Regiflex balloon dilator of a desirable diameter, which is marked with a thick colored marker at the mid-section of the balloon, is passed over the guide wire to the stomach. The endoscope is reinserted to serve as a guide to control the position of the balloon in the esophagus. The balloon is withdrawn to the esophagus, until the mark reaches the gastroesophageal junction. The balloon is inflated up to 12 psi and maintained for 60 s, until an ischemic ring at the LES can be seen by the endoscope through the transparent balloon (Figure 1C). The same inflation procedure is repeated once more and held for another 30 s. The balloon is flattened completely and removed together with the endoscope (Figure 1D). Gastrografin ingestion is performed immediately after the dilation to determine possible esophageal perforation. Chest pains and vital signs are monitored closely. Chest X-rays or computer tomography are carried out should severity of the chest pains imply any possibility of rupture.

Studies on the techniques of Rigiflex balloon dilation of achalasia by positioning the endoscope above the balloon without fluoroscopy have shown results comparable with studies when using fluoroscopy (Figure 2). The advantages are performing this procedure without any extra equipment in a time and cost-effective manner. However, Rai's group[28] has introduced a novel technique by the presence of the endoscope across the gastroesophageal junction during the dilation procedure, with good efficacy reported after dilation. However, despite the safety report from Rai's group, the potential danger of increased perforation is a concern of many other clinicians. Some have argued that such a technique is likely to interfere with the application of uniform radial force on the spastic sphincter. The effect of dilation toward the side of the endoscope can be compromising, and lead to a decrease in overall efficacy of the procedure and the possibility of generating an unequal radial force on the sphincter[40,41].

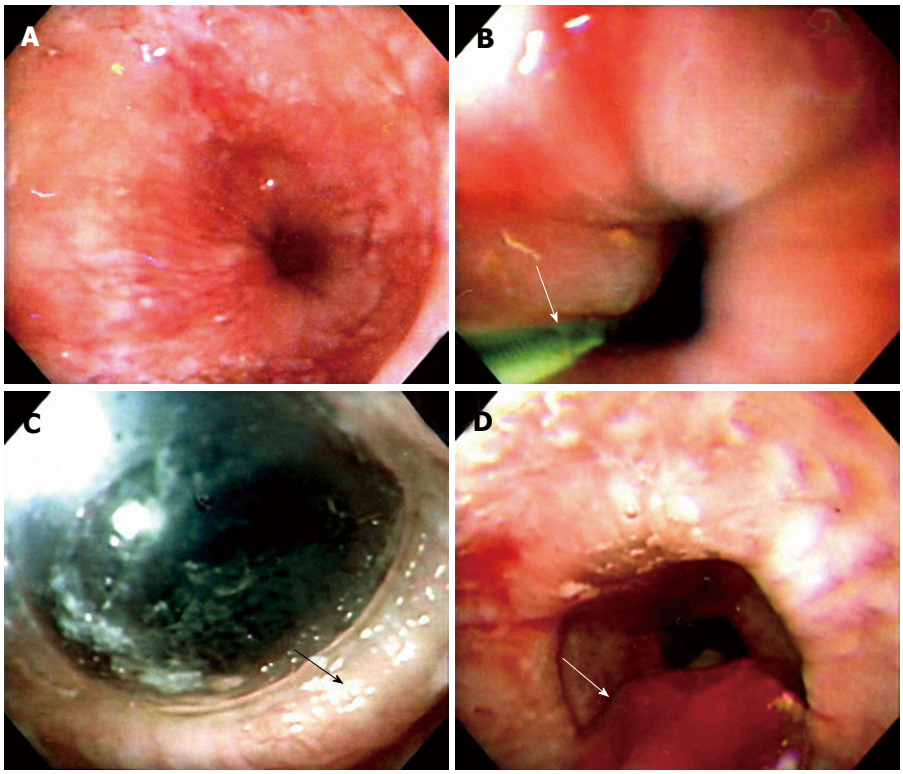

Figure 1 Technique of endoscope-guided pneumatic dilation (PD). A: A dilated low esophageal lumen with tight gastroesophageal junction under endoscope-guided PD; B: The endoscope is inserted down to the duodenum. A guide-wire (arrow) is placed into the duodenum under endoscopic guidance and the endoscope is removed. A Regiflex balloon dilator, which is marked with a thick colored marker at the mid-section of the balloon, is passed over the guide wire to the stomach; C: The endoscope is reinserted to serve as a guide to control the position of the balloon in the esophagus. The balloon is withdrawn to the esophagus, until the mark reaches the gastroesophageal junction. The balloon is then inflated up to 12 psi and maintained for 60 s, until an ischemic ring (arrow) at the LES is seen by the endoscope through the transparent balloon; D: The balloon is flattened completely and removed together with the endoscope (arrow).

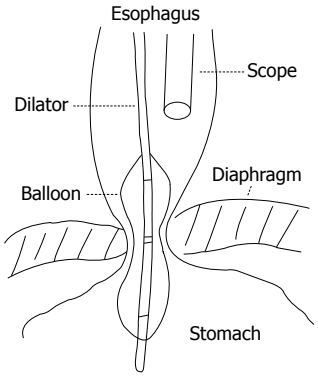

Figure 2 Almost all endoscope-guided PD are performed by using a low compliance Rigiflex balloon dilator by positioning the endoscope above the balloon without fluoroscopy. The advantages are that the procedure can be performed without any extra equipment in a time and cost-effective manner.

POST-DILATION INVESTIGATIONS

Assessment by symptom scores vs esophagography

Usually, structured interviews are performed using validated symptom score methods[10,28,42] at the initial investigation, 6 wk later, and every year thereafter. Depending on whether dysphagia, regurgitation, and chest pain occur occasionally, daily, or several times during the day, a symptom score can be determined. In the system validated by Eckardt[42], a symptom score of 0-3 was assigned to the degree of weight loss. Thus a completely asymptomatic patient would have a symptom score of 0, whereas a severely affected patient could have a high symptom score. In most of these symptom scoring systems, patients were considered to have reached clinical remission if symptoms had totally disappeared or if they had improved by attaining a certain drop in score. Patients who requested further therapy despite having a certain drop in score were considered treatment failures.

A discrepancy between objective parameters and the subjective symptomatic improvement after PD exists in clinical practice. Radiographic findings do not reliably correlate the symptoms to improved esophageal emptying after PD in some large studies[43-45]. However, Vaezi *et al*[46-49] have reported that there was a significant association between improvement in patient symptoms and barium height. They believe that radiographic findings can reliably predict clinical remission and have suggested strongly the need for further treatment in those patients with poor esophageal clearance after each dilation, to avoid possible future complications such as sigmoid-type achalasia.

Large-scale, long-term follow-up investigations[15,50,51] have reported unfavorable recurrence in patients who have undergone fluoroscopic-guided PD. During the prolonged observation period (median, 13.8 years) in a prospective follow-up investigation study conducted by Eckardt *et al*[15], only 40% of patients treated with a single round of PD remained in remission at 5 years. We used endoscope-guided PD to treat achalasia and attained cumulative remissions of 86.7% in first 2 years, which had dropped to 72.9% after 5 years, but it remained at 61.7% in years 6 and 7, but patients were assessed by clinical symptom scores[11]. Bias probably existed when using subjective symptomatic scoring assessment to determine clinical remission. We agree with Vaezi's group who claimed that underscores may occur by only using an objective assessment. However, we believe that esophagography can only offer an additional objective assessment to the response to achalasia treatment, especially in patients who report symptomatic improvement, but the evidence is not strong enough to overthrown the

Table 1 Cumulative effectiveness of endoscope-guided pneumatic dilators for the treatment of achalasia by using low compliance Regiflex dilators

Author (yr)	*n*	Study design	Dilator size (cm)	Improvement (%) (excellent/good)	Follow-up (yr) mean (range)	Perforation (%)
Levine *et al*[25] (1987)	62	Retrospective	3.0-3.5	85/88	-	0
Lambroza *et al*[24] (1995)	27	Retrospective	3.0	67	1.8 (0.1-4.8)	0
Dobrucali *et al*[28] (2004)	43	Prospective	3.0-3.5	54/79	2.4 (0.5-5)	0
Rai *et al*[29] (2005)	56	Prospective	3.5	92.9/89.3	2	0
Chuah *et al*[11] (2009)	32	Prospective	3.0	69/91	4.5 (2.5-7)	3.3

traditional assessment of clinical remission by using subjective symptom score assessment[52]. Although an additional objective parameter such as esophagography to the subjective symptom scores should be more optimal in assessing clinical remission, further investigations that include larger sample sizes and longer follow-up periods are required for clarification of this issue.

Manometric studies

Manometry is an important predictor of treatment failure with balloon dilation, other than younger age (< 40 years), male sex, pulmonary symptoms, and failed response to one or two initial dilations[15,41,53,54]. It has been demonstrated previously that post-dilated LES pressure is relevant to better remission. In general, decreases in LES pressure of > 50% after PD, or an absolute end-expiratory LES pressure of < 10 mmHg, are more indicative of clinical success[15,52,53]. Therefore, it is suggested strongly that manometry be performed routinely before and after PD. One recent advance in the diagnosis of esophageal achalasia is the use of updated high resolution manometry (HRM) with pressure topography plotting[55]. We are optimistic that more promising evidence may emerge on the use of HRM in the near future.

EFFECTIVENESS AND POST-DILATION SAFETY OF ENDOSCOPE-GUIDED PNEUMATIC DILATORS FOR ACHALASIA

Table 1 summarizes studies on the effectiveness of graded endoscope-guided pneumatic dilators for achalasia. Most studies were retrospective except for three prospective, longitudinal cohort studies with a mean follow-up period of 2-4.5 years[11,24,25,28,29]. All studies attained an acceptable clinical remission rate of 54%-91%, which was comparable to those reported by using fluoroscopy-guided PD[32,50,56-59]. Although the existing mid-term follow-up results are encouraging, further long-term follow-up is required in the near future.

The major adverse event caused by PD is esophageal perforation, with a 2% overall cumulative rate, and may occur in up to as many as 5% of all the reported cases of fluoroscope-guided PD[32,49,56-59]. As shown in Table 1, the reported perforation rates was 0%-3.3% for endoscope-guided PD[11,24,25,28,29]. This implies the relative safety of endoscope-guided PD compared to fluoroscope-guided PD. However, esophageal perforation is a potential hazard after PD[60,61]. Usually, gastrografin is ingested immediately after each PD to detect extravasation, which implies the presence of perforation. However, on rare occasions, immediate gastrografin ingestion may not always detect perforation, which can become clinically evident several hours later after delayed presentation (> 24 h)[62,63]. Therefore, we must observe the clinical symptoms and signs closely, such as severe chest pain and fever, which imply the potential presence of perforation after PD.

Reflux symptoms after PD are usually mild and transient and should be easily controlled with proton-pump inhibitors[19]. However, objective assessment of gastroesophageal reflux after PD has rarely been studied. Other complications are usually minor, and include intramural hematoma, diverticula at the gastric cardia, mucosal tears, prolonged post-procedure chest pain, hematemesis without change in hematocrit, fever and angina.

LAPAROSCOPIC MYOTOMY *VS* ENDOSCOPE-GUIDED PD

Like every other treatment of achalasia, the goal of surgery is to assuage the esophageal obstruction by myotomy of the LES. Minimally invasive laparoscopic myotomy with a variety of fundoplication procedures has evolved to be a primary approach for many surgeons and gastroenterologists in a majority of patients with achalasia[64-67]. However, there are only limited systematic reviews and meta-analyses that have compared existing treatment methods for achalasia and all favor surgery to PD[64,68,69]. With overall success rates of 47%-82% at 10 years, laparoscopic Heller myotomy with partial fundoplication appears to have evolved into the surgical procedure of choice[64,65]. Despite this, the major concern for myotomy is still that it can be complicated by severe acid reflux disease, and the role of fundoplication with myotomy continues to be controversial[21,69-72]. Hence, it is generally accepted that myotomy is usually suggested for younger male patients (< 40 years), those with pulmonary symptoms, and those who have failed to respond to one or two initial dilations; older age appears to be associated with favorable outcomes of PD[70,71].

BT INJECTION THERAPY *VS* ENDOSCOPE-GUIDED PD

As a result of its wider safety margin and fewer complications, BT injections have been practiced widely in past decades, with excellent immediate responses (success rates of > 90%). Unfortunately, the duration of response for BT injections is relatively discouraging (6-9 mo on average) in most patients, and only half of all patients benefit for > 1 year[6,10,73]. The effect of BT injections vanishes with time in elderly patients, which necessitates repeated injections to keep the patients symptom-free. As a result of the number of repeated injections required, this procedure is more expensive than PD by ⩾ 50%. However, it has been reported that the long-term success is highest among elderly patients and in those with an LES pressure that did not exceed the upper normal level before treatment[6,10,74,75]. Also, younger patients (< 55 years) with a severe increase in LES pressure do not seem to benefit from BT injections, and PD or minimally invasive myotomy are more advantageous[10]. Generally, minimally invasive myotomy is recommended in younger patients.

In short, PD is more efficacious than BT injections for sustained symptomatic relief in patients with achalasia. BT is as good as PD in achieving a short-term improvement in achalasia. It is also effective in patients with tortuous megaesophagus and previous failed PD. However, as mentioned earlier, recurrence is high during 1-year follow-up[76]. Furthermore, some surgeons may be concerned that previous BT injections make subsequent minimally invasive myotomy riskier and more difficult[77]. Therefore, BT injections are recommended as a suitable alternative only for a minority of older or high-risk patients.

CONCLUSION

Endoscope-guided PD is an efficient and safe nonsurgical therapy with results comparable to other treatment modalities. Besides, it has the advantage that the entire procedure is done without fluoroscopic control, and the mucosal injury during the dilation can be determined by direct visual observation. Long-term follow-up studies are required in the near future.

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