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Pneumatic Dilation versus Laparoscopic Heller's Myotomy for Idiopathic Achalasia

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Summary

Achalasia is a primary esophageal motility disorder which is characterized by impaired relaxation of lower esophageal sphincter and aperistalsis of esophagus. These motor abnormalities result in impaired food bolus transit in the esophagus, which causes symptoms such as dysphagia, regurgitation, chest pain and weight loss. Every year, about 1 in 100,000 people develop achalasia. The exact etiology of achalasia is not entirely clear but an immune mechanism with inflammation and loss of esophageal myenteric neurons has been implicated. To date, the mainstay of treatment of achalasia is the mechanical disruption of the lower esophageal sphincter muscle fibers by either endoscopic pneumatic dilation or surgical myotomy, so as to reduce the lower esophageal sphincter pressure. In recent years, laparoscopic Heller's myotomy (LHM) has been considered to be superior to endoscopic pneumatic dilation for the treatment of achalasia with favorable results from single center studies.[1-3] The addition of Dor's partial fundoplication to Heller's myotomy significantly reduces the incidence of postoperative occurrence of gastroesophageal reflux disease.[4] As a result, LHM becomes the preferred treatment for achalasia especially in United States.

In a prospective multicenter randomized trial that involved 15 centers in 5 countries, the European Achalasia Trial Investigators group compared pneumatic dilation to laparoscopic Heller myotomy.[5] Two hundred and one patients with newly diagnosed achalasia were randomly assigned to pneumatic dilation or LHM with Dor's fundoplication. Symptoms, including weight loss, dysphagia, retrosternal pain and regurgitation, were assessed with the use of the 0-12 point Eckardt score.

The dilation protocol was modified during the early phase of the trial because the initial dilation protocol (35 mm Rigiflex balloon inflated at a pressure up to 8 psi for 1 minute) led to esophageal perforations in 4 of the first 13 patients. All these patients were excluded from the final analysis and a modified 2-session protocol was adopted instead. The patients underwent 30 mm balloon dilation in the first procedure, followed by a 35 mm balloon 1 to 3 weeks later. A third procedure was done using at 40 mm balloon if the Eckardt score was still above 3.

The primary outcome was therapeutic success, which was defined as a drop in the Eckardt score to $\leq$ 3 at the yearly follow-up assessment. The secondary outcomes included the need for retreatment, pressure at the lower esophageal sphincter, esophageal emptying on a timed barium esophagogram, quality of life and the rate of complications.

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Over a mean follow-up time of 43 months, there was no significant difference between the 2 groups in the primary outcome; the rate of therapeutic success with pneumatic dilation was 90% after 1 year of follow-up and 86% after 2 years, as compared with 93% after 1 year and 90% after 2 years in LHM group (P = 0.46). There was no significant difference in the lower esophageal sphincter pressure (LHM, 10 mmHg; pneumatic dilation, 12 mmHg; P = 0.27); esophageal emptying as assessed by the height of column of barium contrast (LHM, 1.9 cm; pneumatic dilation, 3.7 cm; P = 0.21); or quality of life. Abnormal exposure to esophageal acid was observed in 15% and 23% of the patients in the pneumatic dilation and LHM groups, respectively (P = 0.28). The 2 treatment modalities had comparable adverse events. Perforation of the esophagus occurred in 4% of the patients during pneumatic dilation, whereas mucosal tears occurred in 12% during LHM. The predictors of treatment failure included age under 40, preexisting daily chest pain, esophagus less than 4 cm in width, high degree of contrast retention as evidenced by a column higher than 10 cm shown in after-treatment barium esophagogram. In conclusion, LHM with Dor's fundoplication is not superior to endoscopic pneumatic dilation for the primary treatment for achalasia, at least after a mean follow-up period of 43-month.

Comment

This large scale, prospective randomized trial was published in a timely manner when LHM has been increasingly accepted as the initial effective treatment strategy for patients with achalasia. In contrast to the observations of previous single-center studies, this trial reported no significant difference in efficacy between pneumatic dilation and LHM, at least during the initial post-treatment period of 43-month.

The large sample size of this study gave adequate statistical power to detect small difference in efficacy and allowed satisfactory matching of baseline characteristics between the 2 treatment groups of patients. Since this trial was conducted in 15 centers, the results are more readily generalized and applied to real-life clinical practice. The creditability of the results is further supported by the use of both symptomatology and objective tests for evaluation of the treatment response.

Apart from the data on the efficacies of the 2 different treatment strategies, this large scale study also provided high-quality data on the optimum protocol of pneumatic dilation. The high initial perforation rate related to the use of 35 mm balloon lends further support to the use of 30 mm balloon as the optimum size of balloon for pneumatic dilation in treatment-naïve patients. This study also underscored the usefulness of semiquantitative esophageal emptying test as a predictor of treatment failure. In this study, a column of higher than 10 cm shown in after-treatment barium esophagogram was associated with treatment failure.

While this trial has major impact on the current practice, there are also shortcomings. First, this trial compared the 2 different strategies rather than procedures. In the pneumatic dilation group, all participants routinely received at least 2 sessions of dilation and some patients underwent further "on-demand" pneumatic dilations based on the symptom score. This finding may not be extrapolated to populations beyond Europe such as United States and Asia, where both the clinicians and patients may opt for a treatment that can provide effective and durable symptom relief in a single session of treatment. Furthermore, a significant proportion of patients with achalasia develop further relapses of symptoms after the first 2-3 years. Whether the 2 treatment strategies remain comparable in both efficacy and safety is questionable. In a retrospective longitudinal study, it has been reported that the risk of subsequent intervention is greater among persons treated with pneumatic dilation than with surgical myotomy with the difference in complication rates only apparent at 5 years after the initial treatment.[6] Further studies focusing on long-term safety in addition to efficacy are necessary. Lastly, the participants in this study did not have their disease properly sub-categorized with the state-of-the-art high resolution manometry technique, which may give further insights to the relative merits of each treatment strategy in different subgroups of achalasia. For example, patients with esophagus of diameter less than 4 cm were associated with higher treatment failure rate. This group of patients may represent the subgroup of vigorous achalasia, which has been reported to be more resilient to treatment.[7]

How do we apply the findings of this study in the clinical practice? First, patients with achalasia should be offered both options of endoscopic pneumatic dilation or LHM as they have comparable efficacy at least in the intermediate term. The pros and cons of different strategies should be considered and discussed with the patients. The pros of pneumatic dilation include outpatient nature, no anesthesia, shorter recovery time, lower cost and lower risk of gastroesophageal reflux disease. One of the important arguments that favor pneumatic dilation as the initial treatment modality is that it will not undermine the myotomy as a "rescue" procedure, whereas there is still a lack of data on the op-

timum management if surgery fails. On the other hand, LHM may be considered if the patient prefers a single procedure with more durable symptom relief, or the patient is a young male, who is more likely to need re-dilation as observed in this trial.

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