Botox Treatment and Balloon Dilation

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Introduction

Achalasia is a primary esophageal motility disorder featuring poor relaxing lower esophageal sphincter (LES) with aperistalsis of the esophageal body. It is known to result from a selective loss of inhibitory neurons in the Auerbach’s myenteric plexus. The genetic, autoimmune, or infectious theories have been proposed as an etiology. However, the exact mechanism has not been established. Therapeutic options include medication, botulinum toxin injection, pneumatic dilation, surgical myotomy and even POEM (peroral endoscopic myotomy). Among the treatment strategies, this review focuses on our current knowledge with regard to the botulinum toxin injection and pneumatic dilation for the treatment of achalasia.

Balloon dilation

Balloon dilation lowers the LES pressure by tearing muscle fibers. Rigiflex® achalasia balloon dilator diametered of 30, 35, or 40mm, which is larger than that of the TTS (Through-the-scope) balloon is generally used for the procedure to achieve tearing of muscle fibers. A balloon dilator is inserted into the endoscopic accessory channel and positioned at waist area under the fluoroscopy. After the procedure, gastrograffin esophagography is usually performed to check the procedure-related perforation. Before the procedure, meticulous endoscopic examination is essential to exclude the pseudo-achalasia, caused by malignancy. ‘Graded’, ‘On-demand’ or ‘Progressive approach’ is used for dilation.

The short-term efficacy within one or two years was estimated as 71-90%. However, long-term prospective studies revealed more than half of the patients had recurrent symptoms, indicating needs for additional dilation. Repeated procedures have shown to be effective than that of single treatment. However, results of long-term studies are conflicting with regard to the maintenance of efficacy.

The main predictors of the outcome are age and post-dilation LES pressure. Response rates in younger patients (<40 years) have shown to be lower and LES pressure less than 10mmHg was proposed as target of treatment. According to another retrospective study, 30 mm balloon was associated with dilation failure than larger sizes for younger (especially male) patients, indicating 35mm should be the initial step for the procedure in these cases.

Table 1. Predictors of Poor Outcome in Balloon Dilation of Achalasia

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<thead>
<tr>
<th>Related to patient</th>
<th>Related to procedure</th>
<th>Related to manometry</th>
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<tr>
<td>- Young age</td>
<td>- Single dilation</td>
<td>- Type I &amp; III pattern on high resolution manometry (Chicago classification 2012)</td>
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<td>- Dilated sigmoid shape esophagus</td>
<td>- Small size balloon (&lt;30 mm)</td>
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<td>- Failure to lower LES pressure (&lt;10 mmHg)</td>
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Other predictors are dilated sigmoid shaped esophagus, which do not respond well to balloon dilation (Table 1).\textsuperscript{10,13}

With the advancement of high-resolution manometry, achalasia was categorized by 3 types.\textsuperscript{17} Type I, which is a classic achalasia and type II, which shows panesophageal pressurization with \( \geq 20\% \) of swallows have shown a better response to balloon dilation.\textsuperscript{17}

The main procedure-related adverse event is esophageal perforation, which has been reported less than 5\%.\textsuperscript{18} The perforation usually occurs in the first procedure session and the area just above cardia, which is anatomically weak area is the main perforation site.\textsuperscript{18} The instability of balloon or the number of dilation was associated with perforation.\textsuperscript{19} However, the diameter of balloon was not associated with the development of perforation.\textsuperscript{19} Chest pain, reflux symptom, fever, hemorrhage, diverticula, or hematoma could be developed after procedures. The overall rate of these adverse events are known to be less than 10\%.\textsuperscript{18}

For the clinical assessment of effects, Eckardt score is generally used (Table 2). High score indicates pronounced symptom and score less than 3 or 4 has been accepted as therapeutic success.\textsuperscript{20} Vantrappen classification, Adam’s stage, and Watson dysphagia score are another questionnaire for the evaluation of therapeutic effect.\textsuperscript{21} Evaluation of the by the timed barium esophagogram or assessment of esophagogastric junctional distensibility by impedance measurement (called EndoFLIP\textsuperscript{\textregistered}) has been proposed.\textsuperscript{22,23}

### Botulinum toxin injection

Botulinum toxin is the selective inhibitor of acetylcholine which attenuates or blocks the muscular contractions of smooth and striated muscles.\textsuperscript{24} Generally, 1mL of botulinum toxin A (20-25 UI) is injected at each of the four-quadrant area approximately 1cm above Z-line. For the precise targeting of intra-muscular injection, endoscopic ultrasound-guided delivery of botulinum toxin was introduced, although it has not been accepted widely.\textsuperscript{18}

According to a systematic review, the immediate response within a few months seems to be comparable to that of balloon dilation (70-90\%).\textsuperscript{25} However, there has been studies indicating insufficient response of single-injection (symptomatic recurrence after 6-12 months of single botulinum toxin injection) and even studies suggesting inefficiency of repeated botulinum toxin injection.\textsuperscript{26,27} Formation of neutralizing antibody to botulinum toxin has been suggested as the cause of treatment failure or suboptimal response, but the exact mechanism has not been elucidated.\textsuperscript{27}

The predictor of outcome are age and subtype of achalasia. Younger patients are not good candidate than elderly but, vigorous achalasia showed better outcome with BTI than other type of achalasia.\textsuperscript{28} For the Chicago’s classification, type III achalasia showed better response than that of other types.\textsuperscript{29}

The adverse events relevant to botulinum toxin injection are transient chest pain (25\%) and heartburn (5\%). However, there has been no studies indicating risk of generalized neuromuscular blockade.\textsuperscript{30}

### Comparative studies

According to the meta-analysis in 2009, balloon dilation showed better efficacy than botulinum toxin injection.\textsuperscript{31}
However, considering the difficulty of the procedure-technique, economic issue, and safety of procedures, the results cannot be accepted as it stands. According to the Cochrane review, the initial remission rate and mean esophageal pressure within 1 months was not statistically different between balloon dilation and botulinum toxin injection. \(^{32}\) However, balloon dilation showed better response rate in the long-term follow-up period (after 6 months of procedure). \(^{32}\)

**Conclusions**

Balloon dilation and botulinum toxin injection are useful non-surgical methods for the treatment of achalasia. Choice of treatment should be decided considering endoscopist’s experience, type of achalasia, patient’s age, economy and willingness to undergo surgery or multiple procedure.

**References**

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