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Summary

BOTULINUM TOXIN INJECTION IN THE UPPER ESOPHAGEAL SPHINCTER IS HIGHLY EFFECTIVE AND SAFE FOR THE TREATMENT OF R-CPD: RESULTS FROM A RANDOMIZED CONTROLLED STUDY

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Botulinum toxin injection into the upper esophageal sphincter was superior to placebo for treating retrograde cricopharyngeus dysfunction in a randomized triple-blind trial, with 88% of patients achieving at least 50% improvement in ability to belch at 12 weeks compared to 4% with placebo.

KEY POINTS

- At 12 weeks, 88% of patients receiving botulinum toxin (Botox® 75 IU) achieved the primary endpoint of at least 50% improvement in ability to belch versus 4% with placebo, a difference of 84% (95% CI 62-100%, $p < 0.001$).
- Response rates at 1 and 4 weeks were 100% in the botulinum toxin group versus 20% and 4% in the placebo group, and 72% versus 8% at 20 weeks.
- Improvement in belching capacity strongly correlated with improvement in all gastrointestinal symptoms including gurgling noises (Pearson's ρ 0.90), thoracic or abdominal pain (0.85), and excessive flatulence (0.85), all $p < 0.001$.
- A temporary increase in oropharyngeal dysphagia occurred in the treatment group with significantly higher Sydney Swallow Questionnaire scores at 1 week (902 vs. 123, $p < 0.001$) and 4 weeks (421 vs. 109, $p < 0.001$), but there were no serious adverse events.
- The study randomized 50 patients with R-CPD confirmed by manometry with belch provocation test to receive either botulinum toxin or placebo injection via rigid esophagoscopy under short anesthesia.

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