"Onabotulinum Toxin A for Cricopharyngeal Dysfunction in Movement Disorders: A double Blinded Randomized Trial"

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Introduction

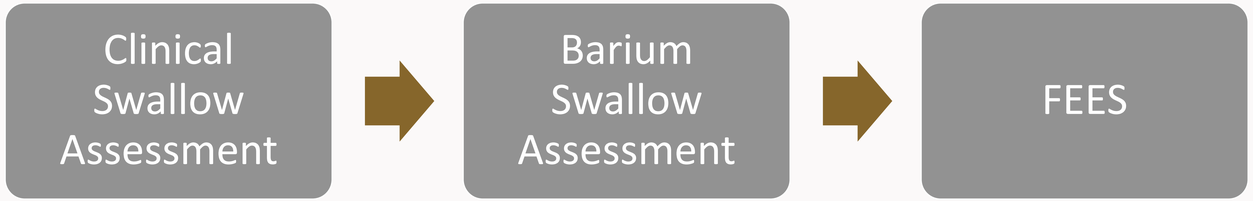
- Swallowing is a highly coordinated neurological process involving sequential and overlapping movements of various craniofacial, pharyngo-esophageal, and laryngeal muscles to facilitate the passage of food and oral secretions from the mouth to the esophagus.
- Any disruption in this coordinated sequence due to neurological disorders can result in swallowing difficulties, categorized as oropharyngeal or pharyngo-esophageal dysphagia.
- The upper esophageal sphincter (UES) plays a vital role in swallowing by temporarily relaxing to allow food passage while being pulled forward and upward by the suprahyoid muscles, ensuring its active opening.
- At rest, the UES remains closed, preventing gastric and esophageal contents from refluxing into the hypopharynx and maintaining airway protection during breathing and between swallowing.
- Impaired relaxation of the cricopharyngeal muscle, known as cricopharyngeal dysfunction (CPD), can lead to swallowing difficulties, weight loss, aspiration pneumonia, airway obstruction, and dependency on alternative feeding methods such as nasogastric tubes or liquid diets.
- CPD significantly affects patients' quality of life and may require medical intervention to prevent serious complications related to malnutrition and aspiration.
- Botulinum toxin injections offer a less invasive treatment than myotomy, but no randomized trials confirm its efficacy and the evidence remains insufficient for definitive clinical recommendations.

Objectives

- The study aims to evaluate the improvement in swallowing function and related parameters, while also monitoring adverse effects such as worsening dysphagia and vocal cord palsy, in patients receiving Botox compared to those receiving a placebo.

Methodology

- Patients were randomly assigned to the intervention (Group 1) or placebo (Group 2) using sealed envelopes.
- Group 1 received onabotulinum toxin (50U in 2 mL saline), while Group 2 received saline.
- After informed consent, patients were evaluated with a symptom questionnaire.
- During endoscopy, botox/placebo were injected in 4 quadrants using a 23G needle. Follow-ups at 3 weeks and 3 months assessed symptoms, swallowing function, repeat endoscopy, and barium swallow outcomes.
- Data were recorded in REDCap for analysis.



Video assessment

Scan QR code

FEES Procedure

Lateral view of a dysphagia patient's barium swallow

AP view of a dysphagia patient's barium swallow

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Results

- At 3-week follow-up:
- 27.3% showed moderate improvement
- 9% showed significant improvement
- 18.2% had minimal improvement
- 45.5% had no meaningful change in swallowing function.
- Improvements were assessed through self-report and biscuit swallowing time.
- No adverse events were reported

Table 1: summarizing the baseline assessment findings

DiagnosisT	Segmental dystonia	Dystonia ataxia	Segmental dystonia	Generalized dystonia	Cervical Dystonia	Acute onset segmental dystonIA
Progression of Dysphagia	no	yes	yes	yes	Yes	Yes
Dysarthria	Yes	Yes	Yes	Yes	yes	Yes
Laryngeal & Hyoid Elevation (Barium swallow)	Present	Present	Present	Present	Present	Present
Pharyngeal Constriction Ratio	0	0	0	0	0	0
PES Opening Duration (s)	0.66	0.733	1.33	0.46	0.4	0.4
PES Opening Size (mm)	8.3	18	11.3	8.5	4.28	4.28
Oro-pharyngeal Transit Time (s)	0.66	0.73	0.4	0.3	0.2	0.2
Hypo-pharyngeal Transit Time (s)	0.73	1.46	1.53	0.6	0.134	0.4
Pharyngeal Diameter at Cricopharyngeus (mm)	13	19	7.1	8.5	20.95	11.44
Pharyngeal squeeze maneuver	Resistance felt	Resistance felt	Resistance felt	Resistance felt	Resistance felt	Resistance felt
Pooling of vallecular secretion	Absent	Absent	Absent	Present	Present	Present

Conclusion

- Botox appears safe and effective for CPD-related dysphagia, especially in dystonia. Further analysis post-unblinding and a larger cohort will strengthen these findings and validate the novel assessment approach.
- Both FEES and barium swallow fluoroscopy are essential for comprehensive dysphagia assessment, and optimizing quantitative parameters will enhance patient outcomes and management.

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