Use of botulinum toxin in voice restoration after laryngectomy
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CRD summary
The review evaluated use of botulinum toxin for voice restoration after laryngectomy and concluded that 70% to 100% of patients with confirmed pharyngoesophageal segment hypertonicity and/or spasm following laryngectomy had improved voice quality; there were few reported complications. The authors’ conclusions should be interpreted with caution because of review process limitations and limited evidence of uncertain quality.

Authors' objectives
To evaluate the safety and effectiveness of botulinum toxin for voice restoration after laryngectomy.

Searching
MEDLINE (from 1966) and The Cochrane Library were searched to January 2009 for publications in English; search terms were reported. Bibliographies of each retrieved article and the authors' personal archives were handsearched.

Study selection
Case series or trials that evaluated use of botulinum toxin for voice restoration in patients with documented voice failure following laryngectomy were eligible for inclusion. Studies were excluded if outcome measures were not fully explained.

Most of the included studies were in North America. All of the included studies performed objective and/or instrumental measurement to confirm hypertonicity or spasm of the pharyngoesophageal segment; the most commonly used method was videofluoroscopy, followed by an air insufflation test. (The authors used the terms pharyngoesophageal hypertonicity and spasm as indicators for botulinum toxin use interchangeably in this review.) Almost half of the studies used local anaesthetic infiltration into the constrictor muscles with resultant improvement in tracheoesophageal puncture voice as a confirmatory step before botulinum toxin injection. Correct positioning of the needle was generally confirmed with videofluoroscopy, but also with electromyogram (EMG) testing. Dose of botulinum toxin varied among studies; most used between 15 and 100 units of Botox and the total injection volume ranged from 0.5mL to 6mL.

The included studies measured improved tracheoesophageal puncture voice as the subjective outcome and used different objective methods, which included: different surgical voice restoration scales; patient qualitative rating of their voice improvement; improvement in stomal pressure; acoustic voice analysis; and improvement in mean phonatory time (other details were reported in the review). The other relevant outcomes were complications.

The authors did not report how many reviewers performed study selection.

Assessment of study quality
No formal validity assessment was performed.

Data extraction
The number of patients (%) who achieved the relative outcome measurement for voice improvement and the number of patients (%) with complications were extracted for each study. The authors did not report how many reviewers performed the extraction.

Methods of synthesis
The percentage of patients who achieved the relative outcome measurement for voice improvement and the percentage of patients with complications were presented as a narrative synthesis as all the included studies measured improved tracheoesophageal puncture voice with different methods.

Results of the review
Nine non-randomised studies were identified (n=134, range five to 62): six prospective studies and three retrospective studies.

All studies reported a maximal toxin effect 72 hours after botulinum toxin injection. An objective improvement in voice production occurred in 70% to 100% patients in the included studies. One study reported that voice improvement in 79% of patients after one injection increased to 89% after a second Botox injection. Another study reported an overall voice improvement of 70% (50% of patients required one injection and 40% of patients required further injections). A third study investigated the duration of the effect and found a mean duration of 20.4 months (range five to 37 months); another study noted a response of up to 11 years in one patient.

Only two patients were reported to have complications: one had dysphagia following bilateral injection and resultant chemical neurectomy; and another suffered from regurgitation while lying flat.

Authors' conclusions
Botulinum toxin can be used as a safe and cost-effective treatment to obtain an improvement in voice quality in patients with confirmed pharyngoesophageal segment hypertonicity and/or spasm following laryngectomy.

CRD commentary
The review addressed a well-defined question in terms of participants, interventions, study design and relevant outcomes. Relevant databases were searched. Only studies published in English were included and it was unclear whether unpublished studies were considered, so some relevant studies may have been missed. Publication bias was not assessed. No formal validity assessment was made and very little relevant information was reported, which made it difficult for the reader to assess the quality of the included studies. The authors did not report any efforts to reduce error and bias in the review process (such as independent screening for relevant studies by more than one reviewer). Some relevant study details were reported, but details such as age and sex of patients were missing. A narrative synthesis was provided due to the heterogeneity in outcome measurement. Although nine studies were identified, they were all very small and none were randomised controlled studies. The authors’ conclusions should be interpreted with caution because of limitations in the review process and limited evidence of uncertain quality.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors identified a need for further relevant studies that accurately recorded preoperative status and surgical techniques and standardised subjective and objective outcome measures.

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