Botulinum toxin A in the treatment of sialorrhea

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CRD summary
The review concluded that the use of intraglandular botulinum toxin A injections is a safe and effective treatment for excessive drooling. Given the methodological weaknesses of the review, the authors’ conclusions should be treated with caution.

Authors' objectives
To evaluate the use of intraglandular botulinum toxin A (BTX) injections in the treatment of sialorrhoea.

Searching
PubMed was searched from 1965 to October 2006; the search terms were reported. The reference lists of included studies were also screened. Only studies in English were eligible for inclusion.

Study selection
Study designs of evaluations included in the review
No specific types of study design were determined in advance of the review. Both controlled and uncontrolled studies were included.

Specific interventions included in the review
Studies of botulinum toxin A (BTX) for the treatment of sialorrhoea were eligible for inclusion. Studies of botulinum toxin B were excluded. The dosage of BTX ranged from 5 to 146 units per parotid gland, and from 15 to 79 units per submandibular gland.

Participants included in the review
Inclusion criteria were not specified in terms of the participants but it was clear that studies of patients with sialorrhoea were eligible for inclusion. The mean age of the participants ranged from 3 to 87 years. Adults with Parkinson's disease, multiple system atrophy and neurologic movement disorders, and children with cerebral palsy were included.

Outcomes assessed in the review
Inclusion criteria were not specified in terms of the outcomes. The included studies assessed reductions in drooling and saliva using various instruments: the drooling quotient, quality-of-life scale, teacher drooling score, Unified Parkinson's Disease Rating Scale, visual analogue scale (VAS), VAS–drooling frequency, VAS–familial embarrassment and VAS–social embarrassment.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
Studies were grouped according to whether they were controlled or uncontrolled. Each study was described in the text and additional information was tabulated.

How were differences between studies investigated?
Differences between the studies were discussed in the text and were apparent from inspection of the tables.

**Results of the review**

Fifteen studies (n=317) were included: 3 randomised double-blind placebo-controlled trials (n=84), one controlled trial (n=45) and 11 uncontrolled studies (n=188).

Three randomised controlled trials and one controlled trial found that the use of BTX improved subjective and objective measures of drooling when compared with placebo or with scopolamine, although only one study found improvement in the group receiving a high dose of BTX. Follow-up was between 1 and 24 weeks. The uncontrolled studies reported similar findings. Reported adverse effects included dry mouth, swallowing difficulties, transient flu-like symptoms, temporary injection site discomfort and thickened saliva.

**Authors’ conclusions**

The evidence indicates that BTX is a safe and effective treatment for excessive drooling.

**CRD commentary**

Inclusion criteria were defined in terms of the intervention but not for the participants, outcomes or study design. Only one electronic database was searched and this was restricted to studies in English, which might have resulted in the omission of other relevant studies. The methods used to select the studies and extract the data were not described, so it is not known whether any efforts were made to reduce reviewer error and bias. Study validity was not assessed, thus it is not known whether the findings are reliable.

The characteristics of the included studies were presented in tabular format. In view of the differences between the studies, a narrative synthesis with studies grouped by study design was appropriate, although the synthesis was mainly a description of the findings of each study in turn. The duration of treatment and follow-up were short and it is therefore not possible to determine the long-term effectiveness of treatment. Given the identified weaknesses of the review, the authors’ conclusions should be treated with caution.

**Implications of the review for practice and research**

Practice: The authors did not state any implications for practice.

Research: The authors stated that further placebo-controlled trials are required to determine the optimum dose, injection location and technique in order that patients may receive maximum benefit from the treatment.

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**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.