Botulinum toxin in the management of sialorrhoea: a systematic review

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CRD summary
The authors concluded that the randomised controlled trials (RCTs) have demonstrated the effectiveness of botulinum toxin in the management of sialorrhoea. Given that some relevant papers might have been missed, there were uncertainties in the review process and the results relied upon two RCTs, the conclusions are unlikely to be reliable.

Authors' objectives
To assess the effectiveness of botulinum toxin (BTX) in the management of sialorrhoea.

Searching
MEDLINE, EMABSE and CINAHL were searched from January 1997 to December 2005 for relevant publications in English; the search terms were reported. Papers not published in peer-reviewed journals were excluded.

Study selection
Studies were required to include at least 16 participants. The included studies assessed BOTX-A (Allergan), BOTX-A (Dysport) or BOTX-B. Treatment doses varied and assessment ranged from 1 to 24 weeks. The majority of studies bilaterally injected BTX into the protid and/or submandibular glands. All studies involved participants with either cerebral palsy, Parkinson's disease, multiple system atrophy, amyotrophic lateral sclerosis or corticobasal degeneration. The included studies were conducted in both children and adults.

The included studies used one or more of the following outcomes to assess sialorrhoea (drooling): visual analogue scale, drooling quotient, drooling rating scale, drooling severity and frequency scale, scintigraphy imaging, bibs used, saliva production, dental rolls, counter measurement and the global impression of change questionnaire. The instruments used to measure outcomes varied between the studies.

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
A narrative synthesis was provided. Tables were used to present study information.

Results of the review
Six studies (n=151) were included: two randomised controlled trials (RCTs) (n=48), two controlled trials (n=65) and two open label studies (n=38).

The studies were heterogeneous with regard to study populations, interventions and outcomes.

The two RCTs compared BTX with placebo. In one RCT BTX-A (Dysport) had a statistically significant effect on drooling for doses of 75 MU per parotid gland, with a median saliva reduction of 50%. The second RCT also reported significant effects for a single dosage regimen for a combination injection into both the parotid and submandibular glands. Side-effects were observed in both RCTs. The remaining studies, at a lower levels of evidence, also reported improvements in outcome measures.
Authors' conclusions
Both RCTs demonstrated the effectiveness of BTX in the management of sialorrhoea. The procedure is minimally invasive and potentially safe. There is no evidence for the superiority of one antigenic type of BTX over another, nor whether injection into parotid or submandibular gland is more advantageous. There is scant evidence for the optimal dose of BTX for each antigenic type.

CRD commentary
The review addressed a clear question and inclusion criteria, in terms of sample size and publication type, were stipulated. The restriction of the literature search to English language papers might have resulted in the omission of some relevant data, as may have the restriction of the review to papers published in peer-reviewed journals for what is a relatively new treatment. The possibility of reviewer error and bias cannot be assessed as the methods used to select studies and extract the data were not described. In addition, it is not possible to comment on the reliability of the results as validity assessment was not undertaken. The quality of most of the included studies was poor, with considerable heterogeneity evident between studies. Given the weaknesses and uncertainties in the review process and the reliance upon two very small RCTs, the conclusions may not be reliable and so 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 larger RCTs, together with a comparison of BTX-A and BTX-B, are required. Future studies should also address different dosage of injection, ultrasound versus no ultrasound guidance, and submandibular versus parotid gland injection.

Funding
Not stated.

Bibliographic details

PubMedID
16911641

DOI
10.1111/j.1749-4486.2006.01263.x

Indexing Status
Subject indexing assigned by NLM

MeSH
Animals; Botulinum Toxins /administration & dosage /therapeutic use; Humans; Injections; Neuromuscular Agents /administration & dosage /therapeutic use; Parotid Gland; Randomized Controlled Trials as Topic; Sialorrhea /drug therapy; Submandibular Gland

AccessionNumber
12006004581

Date bibliographic record published
07/01/2008

Date abstract record published
23/12/2008

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.