Botulinum toxin A for myofascial trigger point injection: a qualitative systematic review

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CRD summary
This review concluded that the present evidence does not support the use of Botulinum toxin A injections for trigger points in myofascial pain. This was generally a well-conducted review and the authors’ cautious conclusions are likely to be reliable.

Authors’ objectives
To assess the efficacy of Botulinum toxin A (BTA) for myofascial trigger point (TP) injection.

Searching
MEDLINE (1966 to 2006), the Cochrane CENTRAL Register (2006), Scopus and CINAHL were searched until June 2006 for articles written in any language; the search terms were reported. The bibliographies of retrieved articles and reviews were checked.

Study selection
Study designs of evaluations included in the review
Double- or single-blind randomised controlled trials (RCTs) were eligible for inclusion. Only trials with 10 or more participants were eligible for inclusion. Open-label clinical trials, case series, case reports, reviews, expert opinions and abstracts were excluded. The included studies were double-blind RCTs; one study had a crossover design.

Specific interventions included in the review
Studies of BTA for myofascial TPs compared with active or inactive controls were eligible for inclusion. All included studies were of BTA compared with saline injection. The volume of BTA injected ranged from 0.05 to 6 mL, with BTA concentrations ranging from 5 to 150 U. Where reported, concurrent therapies included paracetamol, physical therapy, or a standardised regimen of amitriptyline, ibuprofen and propoxyphene-acetaminophen.

Participants included in the review
Studies of participants undergoing treatment for TP were eligible for inclusion. The definition of TP used varied between trials. Studies of patients treated for muscle spasm and pain with no mention of TP were excluded. The mean age of the participants ranged from 38.1 to 46.6 years. The duration of pain ranged from more than 6 months to a mean of 8.6 years. Where reported, 67% of the participants were female. Pain location was neck and shoulder, cervical and cervico-thoracic.

Outcomes assessed in the review
Outcomes eligible for inclusion were not clearly defined. The outcomes reported were use of rescue medication, pain, mood, range of motion and assessment of improvement. A variety of standardised and non-standardised measures were used.

How were decisions on the relevance of primary studies made?
One author read the retrieved abstracts and selected studies for inclusion. Reasons for study exclusion were reported in the review. Both authors subsequently read all of the included articles to check their eligibility.

Assessment of study quality
Validity appears to have been assessed by more than one reviewer, with any discrepancies resolved by discussion. Validity was assessed using the Oxford Pain Validity Scale (OPVS), a 5-item scale assessing blinding, size of groups, outcomes, appropriate and sensitive baseline measures, and data analysis. A maximum score of 16 can be achieved. The quality of the included trials was assessed using the Jadad criteria, which assesses randomisation, blinding and withdrawals. The maximum achievable score is 5.

Data extraction
Two authors independently read the articles. It is unclear whether the data extraction was independent. Data on study outcomes and authors' conclusions were extracted. Overall study results were classed as either positive or negative.

**Methods of synthesis**

*How were the studies combined?*

The studies were combined in a narrative.

*How were differences between studies investigated?*

Differences between the studies were discussed in the text and reported in the tables.

**Results of the review**

Five RCTs (n=257) were included: four studies used a parallel design (n=241) and one used a crossover design (n=16).

One study scored the maximum of 5 on the Jadad scale, four scored 4 and one scored 2. One study scored the maximum 16 on the OPVS, three scored between 12 and 14, and one scored 8.

Four of the studies found no significant differences between BTA and control groups on all measures. One study found a significant improvement in pain at 4 weeks post-injection in the BTA group (no p-values reported). However, this study scored poorly on the OPVS (8 out of 16), which suggests that the findings may not be reliable.

**Authors' conclusions**

The current evidence does not support the use of BTA for myofascial TP.

**CRD commentary**

The review question and inclusion criteria were clear and well-defined. An appropriate search was carried out using multiple databases with no language restrictions applied, thereby minimising the likelihood of important studies being missed. However, only published studies were eligible for inclusion, which introduces the risk of publication bias. Study quality was assessed using two standardised scales, and aspects of study design affecting reliability and validity were also discussed in the text. The study selection and validity assessment processes were carried out by more than one reviewer, but there is insufficient detail to determine whether the data extraction was carried out independently. The possibility of error and bias at this stage of the review process cannot, therefore, be ruled out. There was a high level of heterogeneity between the included studies in outcome measures, dosages, inclusion criteria and location of TPs, thus the decision to combine the results in a narrative was appropriate. This was a generally well-conducted review and the authors' cautious conclusions are likely to be reliable.

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

Practice: The current evidence does not support the use of BTA injections for myofascial TP.

Research: Further adequately powered double-blinded and appropriately randomised RCTs are needed that control for concurrent therapies and psychosocial factors. Further studies are needed to determine the appropriate dosage, injection technique and injection volume.

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