TITLE: Botulinum Toxin A for Myofascial Pain Syndrome: A Review of the Clinical Effectiveness

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CONTEXT AND POLICY ISSUES:

Botulinum toxin is a potent neurotoxin that causes muscle paralysis by blocking the release of acetylcholine at neuromuscular junctions. Botulinum toxin occurs in several subtypes, with type A and B being used in clinical practice since 1989. Botulinum toxin A was marketed in two distinct formulations, Botox® and Dysport®. Minute amounts of botulinum toxin A have been used to decrease muscle spasm and pain in various pain syndromes. The use of botulinum toxin A for myofascial pain syndrome, an off-label indication, requires a review of its clinical effectiveness.

RESEARCH QUESTIONS:

What is the clinical effectiveness of botulinum toxin A for reduction in pain and improvement of functioning in myofascial pain syndrome?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, OVID’s Embase, the Cochrane Library (Issue 3, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and September, 2008, and are limited to English language publications only. Filters were applied to limit the retrieval to health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, other controlled clinical trials, and observational studies. Internet links are provided, where available.
SUMMARY OF FINDINGS:

Our literature search identified one systematic review on the efficacy of botulinum toxin A for myofascial pain syndrome\(^8\) and five recent randomized controlled trials (RCTs).\(^9\)-\(^{13}\) The qualitative systematic review, with literature search ending in 2006, and covering five placebo-controlled RCTs including 260 patients, concluded that evidence cannot support the use of botulinum toxin A injection in trigger points for myofascial pain.\(^8\)

The five RCTs that were not included in the above systematic review studied the effectiveness of botulinum toxin A in reducing myofascial pain as compared to placebo.\(^9\)-\(^{13}\) Four out of five trials reported that botulinum toxin has no effect on pain, or the effect is not statistically significant. It is noteworthy, though, that the only trial that reported a statistically significant improvement in myofascial pain used Dysport\(^\text{®}12\) as opposed to Botox\(^\text{®}\), which was used in the other four trials. Results from the trials are summarized in Table 1.

**Table 1: Results from the RCTs on the Use of Botulinum Toxin A for Myofascial Pain**

<table>
<thead>
<tr>
<th>Studies</th>
<th>Number of patients/Follow up time</th>
<th>Results</th>
<th>Statistical significance</th>
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<tbody>
<tr>
<td>Lew et al.(^9) (2008)</td>
<td>29 patients/6 months</td>
<td>Botulinum toxin A reduces pain</td>
<td>Difference not statistically significant</td>
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<tr>
<td>Kurtoglu et al.(^10) (2008)</td>
<td>24 patients/4 weeks</td>
<td>Botulinum toxin A reduces pain</td>
<td>Difference not statistically significant</td>
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<tr>
<td>Guarda-Nardini et al.(^11) (2007)</td>
<td>20 patients/6 months</td>
<td>Botulinum toxin A reduces pain</td>
<td>Difference not statistically significant</td>
</tr>
<tr>
<td>Göbel et al.(^12) (2006)</td>
<td>145 patients/6 weeks</td>
<td>Botulinum toxin A reduces pain</td>
<td>Difference statistically significant</td>
</tr>
<tr>
<td>Qerama et al.(^13) (2006)</td>
<td>30 patients/4 weeks</td>
<td>Botulinum toxin A has no effect on pain</td>
<td>Not applicable</td>
</tr>
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</table>

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

Based on the systematic review and four of the five RCTs that were identified,\(^9\)-\(^{11,13}\) the current clinical evidence does not suggest that botulinum toxin A is effective for the treatment of myofascial pain syndrome. The one RCT that used Dysport\(^\text{®}\) found a significant reduction in myofascial pain.\(^12\) Head-to-head randomized trials comparing Botox\(^\text{®}\) and Dysport\(^\text{®}\) suggested they are not bioequivalent.\(^14\) This may explain the discrepancy in the efficacy of different formulations of botulinum toxin A in the treatment of pain for myofascial pain syndrome. The results of the RCTs and systematic reviews should be considered when deciding whether to use botulinum toxin A for treatment of myofascial pain syndrome.

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