



TITLE: Botulinum Toxin A for Migraine Headaches: Clinical Effectiveness

DATE: 31 January 2012

RESEARCH QUESTION

What is the clinical effectiveness of botulinum toxin A for reduction in pain and improvement of functioning in patients with migraine headache?

KEY MESSAGE

Evidence is inconclusive regarding the clinical effectiveness of botulinum toxin A for reduction in pain and improvement of functioning in patients with migraine headache.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2012, Issue 1), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and abbreviated list of major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between Sept 1, 2008 and Jan 25, 2012. Internet links were provided, where available.

RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and non-randomized studies.

One meta-analysis, eight randomized controlled trials, and one non-randomized study were identified pertaining to the clinical effectiveness of botulinum toxin A for reduction in pain and improvement of functioning in patients with migraine headache. No relevant health technology assessment reports were identified. Two pooled analyses were identified that reported on the PREEMPT studies and are included in the appendix.

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Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

1. Shuhendler AJ, Lee S, Siu M, Ondovcik S, Lam K, Alabdullatif A, et al. Efficacy of botulinum toxin type A for the prophylaxis of episodic migraine headaches: a meta-analysis of randomized, double-blind, placebo-controlled trials. *Pharmacotherapy*. 2009 Jul;29(7):784-91.
[PubMed: PM19558252](#)

Randomized Controlled Trials

2. Cady RK, Schreiber CP, Porter JA, Blumenfeld AM, Farmer KU. A multi-center double-blind pilot comparison of onabotulinumtoxinA and topiramate for the prophylactic treatment of chronic migraine. *Headache*. 2011 Jan;51(1):21-32.
[PubMed: PM21070228](#)
3. Chankrachang S, Arayawichanont A, Pongvarin N, Nidhinandana S, Boonkongchuen P, Towanabut S, et al. Prophylactic botulinum type A toxin complex (Dysport(R)) for migraine without aura. *Headache*. 2011 Jan;51(1):52-63.
[PubMed: PM21083558](#)
4. Lipton RB, Varon SF, Grosberg B, McAllister PJ, Freitag F, Aurora SK, et al. OnabotulinumtoxinA improves quality of life and reduces impact of chronic migraine. *Neurology*. 2011 Oct 11;77(15):1465-72.
[PubMed: PM21956721](#)
5. Aurora SK, Dodick DW, Turkel CC, DeGryse RE, Silberstein SD, Lipton RB, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. *Cephalalgia*. 2010 Jul;30(7):793-803.
[PubMed: PM20647170](#)
6. Diener HC, Dodick DW, Aurora SK, Turkel CC, DeGryse RE, Lipton RB, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. *Cephalalgia*. 2010 Jul;30(7):804-14.
[PubMed: PM20647171](#)
7. Magalhaes E, Menezes C, Cardeal M, Melo A. Botulinum toxin type A versus amitriptyline for the treatment of chronic daily migraine. *Clin Neurol Neurosurg*. 2010 Jul;112(6):463-6.
[PubMed: PM20399553](#)

8. Mathew NT, Jaffri SF. A double-blind comparison of onabotulinumtoxinA (BOTOX) and topiramate (TOPAMAX) for the prophylactic treatment of chronic migraine: a pilot study. *Headache*. 2009 Nov;49(10):1466-78.
[PubMed: PM19912346](#)
9. Millan-Guerrero RO, Isais-Millan S, Barreto-Vizcaino S, Rivera-Castano L, Rios-Madariaga C. Subcutaneous histamine versus botulinum toxin type A in migraine prophylaxis: a randomized, double-blind study. *Eur J Neurol*. 2009 Jan;16(1):88-94.
[PubMed: PM19087155](#)

Non-Randomized Studies

10. Oterino A, Ramon C, Pascual J. Experience with onabotulinumtoxinA (BOTOX) in chronic refractory migraine: focus on severe attacks. *J Headache Pain [Internet]*. 2011 Apr [cited 2012 Jan 30];12(2):235-8. Available from:
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3072485>
[PubMed: PM21298315](#)

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APPENDIX – FURTHER INFORMATION:

Pooled Analyses Based on the PREEMPT Trials

11. Aurora SK, Winner P, Freeman MC, Spierings EL, Heiring JO, DeGryse RE, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled analyses of the 56-Week PREEMPT clinical program. *Headache*. 2011 Oct;51(9):1358-73.
[PubMed:PM21883197](#)

12. Dodick DW, Turkel CC, DeGryse RE, Aurora SK, Silberstein SD, Lipton RB, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. *Headache*. 2010 Jun;50(6):921-36.
[PubMed: PM20487038](#)