IncobotulinumtoxinA for Upper Limb Spasticity: Clinical Effectiveness
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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada’s health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Research Question

What is the clinical effectiveness of incobotulinumtoxinA for upper limb spasticity in adults?

Key Findings

One systematic review and two randomized controlled trials were identified regarding the clinical effectiveness of incobotulinumtoxinA for upper limb spasticity in adults.

Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval to by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2009 and January 10, 2018. Internet links were provided, where available.

Selection Criteria

One reviewer screened citations and selected studies based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Population</th>
<th>Adults with upper limb spasticity (including post-stroke spasticity)</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>IncobotulinumtoxinA (Xeomin)</td>
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<tr>
<td>Comparators</td>
<td>• Other botulinum toxin A products (abobotulinumtoxinA [Dysport], onabotulinumtoxinA [Botox], botulinum toxin A biosimilar [Nabota]); • Placebo</td>
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<tr>
<td>Outcomes</td>
<td>• Functional or disability outcomes (e.g., Modified Ashworth Scale [MAS], Tardieu Scale score [TSS], active range of motion, Disability Assessment Scale [DAS], Modified Frenchay Scale [MFS], ease of applying a splint, Goal Attainment Scale [GAS], need for restraints); • Physician Global Assessment; • Symptoms (e.g., pain); • Health-related quality of life as measured by validated scales (e.g., SF-36, EQ-5D); • Duration of effect and re-treatment intervals; • Harms (e.g., AEs, SAEs, WDAEs, Mortality, add notable harms/harms of special interest [antibodies, injection site reaction, muscle weakness, dysphagia, etc.])</td>
</tr>
<tr>
<td>Study Designs</td>
<td>Health technology assessments, systematic reviews, meta-analyses, randomized controlled trials</td>
</tr>
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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.

One systematic review and two randomized controlled trials were identified regarding the clinical effectiveness of incobotulinumtoxinA for upper limb spasticity in adults. No relevant health technology assessments were identified.

Additional references of potential interest are provided in the appendix.

Overall Summary of Findings

One systematic review and two randomized controlled trials (RCTs) were identified regarding the clinical effectiveness of incobotulinumtoxinA (A/Inco) for upper limb spasticity in adults.

The authors of the identified systematic review examined the efficacy and safety of botulinum neurotoxin, with their panel concluding that A/Inco had a level B recommendation for use in the treatment of upper limb spasticity.

The authors of the two identified RCTs examined the efficacy and safety of A/Inco compared with placebo. In both RCTs, A/Inco had more patients that improved in the primary target clinical pattern (PTCP) Ashworth scale (AS) scores when compared with placebo after four weeks. In one RCT, there were larger improvements on these PTCP AS scores with A/Inco. A/Inco was also associated with functional improvements; however, there were slightly greater numbers of mild to moderate adverse events when compared to placebo. The authors of the second RCT observed statistically significant odds ratios that favoured the use of Inco/A for all flexor muscle groups at week four, with significant results favouring Inco/A at week 12 in the principal therapeutic target, the global assessment of efficacy, and for some tasks in the Carer Burden Scale. Adverse events were comparable between placebo and Inco/A in the second RCT.

References Summarized

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses


Randomized Controlled Trials

PubMed: PM19644361
Appendix — Further Information

Previous CADTH Reports


Systematic Reviews and Meta-Analyses – Unclear Intervention


Randomized Controlled Trials

Alternative Comparator


Clinical Trials Registry - No Publications Identified


Review Articles


Additional References
