PICO Questions
1) In children with Cerebral Palsy, does usual care with the use of upper extremities (UEs) Botox injection in comparison to usual care affect upper extremity function and/or postpone surgical intervention?
2) In children with Cerebral Palsy, does usual care with lower extremities (LEs) Botox injection in comparison to usual care affect lower extremity function and/or postpone surgical intervention?

How was the review conducted?
A database literature search was conducted in December 2006 using the following search terms: Child and (Botox or botulism or botulinum) and 3) Cerebral Palsy. The search including articles published from 1999 to 2007 was conducted in the following database: (Embase, Medline, CINALH and PsyInfo). Nine articles closely related to the PICO questions were identified of which six were selected for review.

Section 1 – Summaries of articles reviewed
Question 1: Articles related to upper extremities

This best evidence synthesis assessed the evidence of design and methodology quality, type of outcome measures, and statistical significance of the results of the studies. The review included 3 Randomized Control Trials (RCT) and 12 uncontrolled studies. Short term (up to 3 mos.) and long term (longer than 3 mos.) outcomes were reviewed. No evidence was found to support any short term or long-term effects of botulinum toxin type A injection on spasticity/tone, ROM or activity (skill). Problems included lack of reliable and valid measures of muscle tone, inter-intra reliability of modified Ashworth scale (spasticity measure), insufficient statistical power of results, small sample sizes with considerable variation in location/severity of atypical muscle tone and age of participants, and no consensus in literature of how to measure upper limb function on children with CP. Some skill outcome measures used reflect compensation rather than improvement in paretic limb function, and other measures specifically address skills related to dominant hand.

The purpose of the study was to determine the efficacy and tolerability of botulium toxin in children with cerebral palsy in reducing spasticity and improving upper limb function. This was a cohort study of 11 children with Cerebral Palsy, 7 boys and 4 girls, age range 2 -15.5 years (9 with hemiplegia, 1 with spastic diplegia, 1 with spastic triplegia) who had had no change in upper limb function for the 3 mos. prior to intervention, moderate spasticity and no joint contractures. The intervention involved injection of Botox into specific muscles based on clinical judgments related to the degree of spasticity and short term goals (not defined). Participants received PT and other services throughout. Measures included pre and post-test measures of spasticity and parent assessment of improvement for all participants; other parameters included various range of motion and functional assessments, which were administered for some participants. A statistically significant decrease in mean spasticity scores for injected muscles was reported after injection, with increases in range of motion. Onset of effects was less than 24 hours, the peak effect was in 2 weeks post injection and improvements persisted for 6 mos. Limitations included lack of knowledge of standardized dosages and benefits/dangers of specific dosages used.


The purpose of the study was to investigate the effect of BTA injections in the upper limbs of children with cerebral palsy on their movement patterns, functional skills and self-care capabilities. This is a case control study involving 15 children, aged 4-13 years old with diagnoses of diplegia (9), hemiplegia (2) and quadriplegia (4). Following baseline evaluation, participants participated in 12 weeks of PT/OT (not specifically described), were re-evaluated, administered Botox injections (dosage determined by size of the muscle, severity of spasticity and desired effect) with continued OT/PT, and reevaluated at 6 weeks and 12 weeks post injections. Evaluation measures included Modified Ashworth Scale (spasticity), PEDI (self care and caregiver assistance), measure of hand and pinch strength, range of motion (ROM) and a speed and dexterity measure (BOTMP). Results indicated significantly reduced spasticity of treated muscles, improvements in PROM in the 12-week period, and significant improvement in speed/dexterity at 6-12 wks. Care assistance for self-care, grasp strength and pinch changes were not significant.

**Question 2: Articles related to lower extremities**


This was a retrospective chart review of children with CP treated at one center in Belgium to assess the impact of gait analysis and Botox on age of surgeries. Children included in the study were between the ages of 7 and 9 during three phases of treatment approaches (standard, with gait assessment and with Botox). They found that both the inclusion of gait assessments and the use of Botox delayed necessary surgery for the 424 cases reviewed. They recommend multiple level treatments approach that should start at an early age; primary motor problems should be treated with Botox to delay the onset of secondary problems. Surgery should be delayed till gait pattern matures (9 years).
There is strong evidence of decrease spasticity and increase range of motion with LE BTA Injections.

Section 2 – Implications for Practice

1. Summary:
There are few studies supporting the efficacy of BTA injections for children with CP in terms of functional outcomes, and especially for the use of BTA injections in upper extremities. Positive outcomes of treatment that are most consistently reported include a decrease in muscle tone and an increase in range of motion. The maximum benefit is seen from 2 weeks to 3 months but persists for about 6 months. Children younger than 48 months and those with less spasticity show the most improvement. Children with hemiplegia and diplegia showed more improvement with lower extremity BTA injection. Use of BTA in the lower extremities can delay surgery. Physicians administer dosages of BTA based on size of muscle, degree of spasticity and treatment goals for the individual child. All studies of BTA injections in upper and lower extremities of children with CP involved ongoing PT or OT throughout the course of treatment. There is a need for further studies involving homogeneous populations (e.g. age, severity and distribution of spasticity), and more reliable and consistent outcome measures. The type of PT/OT intervention and the impact of other co-occurring treatments need to be further studied. Videotaping and Goal Attainment Scaling are promising methods to assess functional improvement.
2. **Trustworthiness of studies’ results:**
The systematic review published in 2006, indicated that there were only 3 RCT and 13 controlled studies that met the criteria for research design, methods and statistical significance of results. Studies involved small sample sizes, a range of age of participants, and use of a variety of measures for baseline and outcome measures. The number of muscles injected and the dosage administered was not consistent. The findings were ambiguous related to most common outcome measures, including tone, ROM and activities. In the other studies we reviewed, content and intensity of co-occurring therapy is not described in detail weakening the designs of these studies. Most notably, the studies used outcome measures with questionable psychometric properties. There is no Gold Standard assessment for spasticity in children with cerebral palsy, although the modified Ashworth Scale is most consistently used. Functional skill assessments, especially of upper extremity function, often involve tasks typical of the dominant hand.

3. **Level of Evidence:**
There is a 2a level of evidence for lower extremity BTA injections and a 4 level of evidence for upper extremity BTA injections according to the criteria from Sackett and colleagues (2000).

**TAKE-HOME MESSAGE**

It is believed that BTA injections provides a “window of opportunity” for children to practice moving their limbs with decreased impediment from spasticity and hopefully improve their motor control. There is strong evidence that BTA injections can temporarily decrease muscle tone and improve range of motion in children with CP with better evidence for LEs than for UEs. The evidence of functional gains following BTA injections is moderate for LEs and weak for UEs. Younger children may make greater gains in gait patterns and in acquisition of fine motor and self care skills. BTA injections can help postpone LEs surgery. There are minimal risks of BTA injections for children with CP and negative effects if they occur are temporary as the effect of BTA injections typically wear off within 3 to 6 months.

Physicians, families and therapists can collaborate in assessing the potential benefit of BTA injections for a specific child and monitoring improvement post injections. Considering the limited evidence of functional improvements following BTA injections, we suggest that therapists systematically collect data to track changes including making short videos of the child pre and post BTA injections. Although this is not fully supported in the literature, the children will likely benefit from OT and/or PT services after BTA injections to capitalize on the “widow of opportunity”.

Further information can be obtain from: