



3-2019

## Benefits and Risks of Botulinum Toxin-A Injections for Tone Management

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### WMU ScholarWorks Citation

Perlaki, Brittany and Soens, Kate, "Benefits and Risks of Botulinum Toxin-A Injections for Tone Management" (2019). *Occupational Therapy Graduate Student Evidenced-Based Research Reviews*. 46. [https://scholarworks.wmich.edu/ot\\_posters/46](https://scholarworks.wmich.edu/ot_posters/46)

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# Benefits and Risks of Botulinum Toxin-A Injections for Tone Management

Brittany Perlaki & Kate Soens

## Background Information:

Botulinum Toxin-A (BoNT/A) is being used as an adjunct to therapy to reduce focal spasticity, increase range of motion (ROM), manage pain, improve function, and possibly delay surgical intervention (Hoare & Imms, 2004). BoNT/A inhibits acetylcholine release at the neuromuscular junction resulting in temporary denervation and decreased muscular activity. Reinnervation eventually restores muscle function. Adverse effects include excessive weakness and atrophy of injected muscle, unintended weakness in adjacent muscles, and immunoresistance to BoNT/A (Ghasemi, Salari, Khorvash, & Shaygannejad, 2013).

## 1 Ask: Research Question

What are the benefits and risks of using BoNT/A injections to manage tone?

## 2a Acquire: Search Terms

**Databases:** ProQuest, PubMed, ClinicalKey

- **Patient/Client Group:** Hypertonicity
- **Intervention:** Intramuscular Botulinum Toxin-A injections
- **Comparison:** Placebo Injection or another active OT treatment
- **Outcome(s):** Pain, tone, active range of motion (AROM), disability or function

## 2b Acquire: Selected Articles

**Hoare & Imms (2004):** Systematic review of BoNT/A injections to reduce tone and improve upper extremities functional use in children with cerebral palsy.

**Singh & Fitzgerald (2010):** Systematic review and meta-analysis investigating the efficacy and safety of BoNT/A compared to placebo or active treatment in people with post-stroke shoulder pain.

## 3a Appraise: Study Quality

**Hoare & Imms (2004):** Level one evidence including two randomized control trials (RCT), four case studies, and nine single group designs. Studies used varied assessment tools but some lacked reliability and validity. RCT1 was double blind but limited by small sample size (n=14). RCT2 was single blind but used reliable and valid functional measures. Most of the single group designs poorly controlled for confounding variables. No study clearly defined occupational therapy (OT) interventions used, which limits reproducibility.

**Singh & Fitzgerald (2010):** Level one evidence. Twenty-one studies qualified for full review, 15 were excluded for myofascial pain. Six studies met the inclusion criteria, labeled as "double-blind" RCT's. Sample size n= 17-43 participants. Most of the studies did not use valid and reliable outcome measures. Four of the six studies were partially funded by the makers of BoNT/A. Interventions were not consistent between studies and outcome measurements were not clearly defined.

## 3b Appraise: Study Results

**Hoare & Imms (2004):** RCT1 demonstrated statistically significant ( $p < .05$ ) improvements in tone and spasticity of the wrist and elbow, AROM elbow extension and thumb extension, and grasp and release scores. RCT2 found statistically significant improvements in quality of movement and functional ability in self care; 13.3%  $\wedge$  in QUEST score & PEDI ( $F=4.68$ ,  $df=1,82$ ;  $p=.04$ ). Single group designs demonstrated statistically significant improvement in spasticity, ROM, fine motor skills, disability, and self care skills. Temporary adverse effects included two cases of excessive localized weakness and two cases of generalized upper extremity weakness.



(Spinal Cord Injury BC, 2019)

**Singh & Fitzgerald (2010):** BoNT/A was associated with significantly greater reduction in pain compared to the control at four to six weeks; estimated significance MD -0.9 favoring BoNT/A over placebo (95% CI -1.8 to -0.1;  $p= 0.03$ ). External rotation improved significantly more in the BoNT/A group compared to the control in three RCTs at four to six weeks (MD 9.79°). No significant differences were noted in muscle spasticity, adverse events, shoulder flexion or shoulder abduction. Interpretation of these findings is limited due to few studies with small sample sizes.

## 4 Apply: Conclusions for Practice

**Hoare & Imms (2004):** BoNT/A injections temporarily decrease tone creating opportunity for therapists to impact ROM, reduce deformity, and make functional gains. Research supports BoNT/A injections adjunct therapy achieves clinically significant gains in children with spastic cerebral palsy with minimal risks, but not all individuals will benefit. Further research with defined therapy protocols, valid and reliable assessment tools, and multiple injections is necessary for efficacy of specified therapeutic intervention techniques adjunct BoNT/A injections (Hoare & Imms, 2004).

**Singh & Fitzgerald (2010):** BoNT/A injections may be useful in decreasing shoulder pain and increasing external rotation in patients post-stroke; this allows patients to withstand further stretching, reach greater functional changes and engage more independently in occupational activities. More studies with larger sample sizes and longer follow ups are needed to confirm these findings before BoNT/A can be fully supported as an effective intervention for patients with shoulder pain associated with hemiplegia.

## References:

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- Hoare, B., & Imms, C. (2004) Upper-limb injections of botulinum toxins-A children with cerebral palsy: A critical review of the literature and clinical implications for occupational therapists. *American Journal of Occupational Therapy*, 58, 389-397.
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BoNT/A injections coupled with therapy reduce pain and tone and increase active range of motion and function in individuals with hypertonicity.

