

# Effect of Upper Limb BTX-A on HRQOL in Hemiplegic CP

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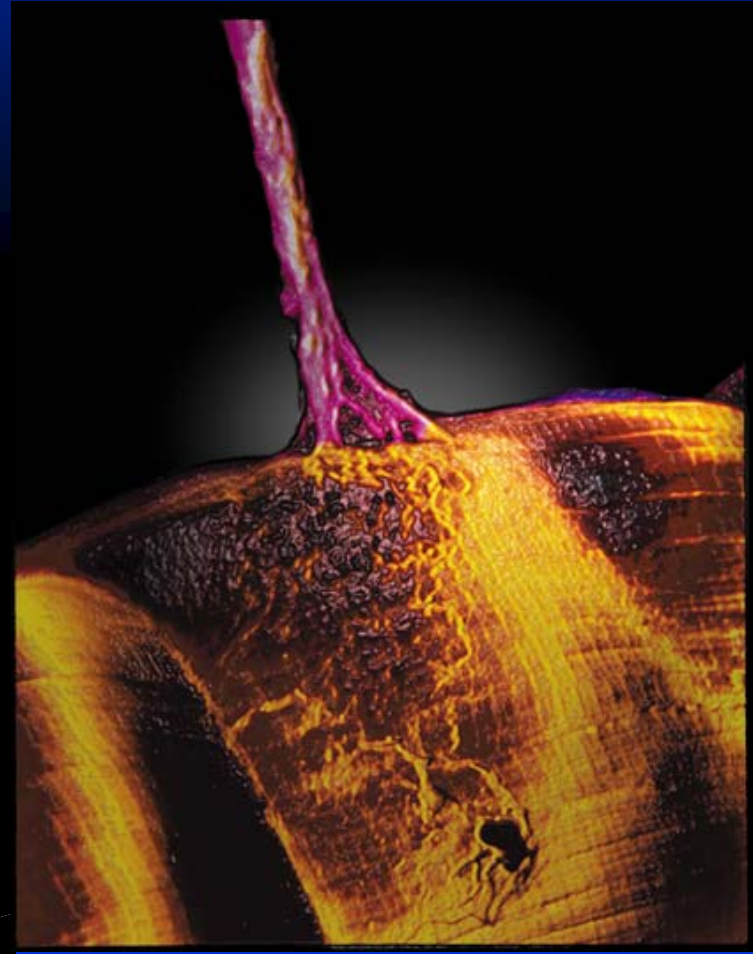
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# Background

- **Cerebral palsy** – most common cause physical disability in children
- **Spasticity** - ↓ function
  - contractures
  - bony malalignment
- **Botulinum toxin A (BTX-A)**
  - LL spasticity (PBS)
  - UL spasticity (increasing evidence efficacy)

# Botulinum Toxin A (BTX-A)

- Neurotoxin
- Clostridium difficile
- Binds motor nerve ending
- Reversible
- Peak 3-4 weeks



# Health Related Quality of Life (HRQOL)

- *“individual’s perception of their health”* (Irrgang et al 2002)
- Physical, social, emotional and role functioning
- *Essential health outcome clinical trials*<sup>WHO</sup>
- Not correlated with function

# HRQOL - Child with CP

- Heterogenous disorder
  - physical disability
  - cognitive impairment
  - comorbidities
- Developmental considerations
- Family function

# HRQOL Tools

- Generic
  - comparison broad patient populations
  - strong measurement properties
- Disease specific
  - responsive to clinically important aspects of care
- Parent proxy
- Child self-report

# PedsQL

- *Pediatric Quality of Life Inventory*
- Version 4.0 **Generic Core Scales**
- Version 3.0 **Cerebral Palsy** Module
- Forms:
  - Toddler (2-4y), Young Child (5-7y),  
Child (8-12y), Teen (13-18y)
- Child Self-report and Parent Proxy forms

# PedsQL – 4.0 Generic Core Scales

- Scales:

Physical Functioning (8 items)

Emotional Functioning (5 items)

Social Functioning (5 items)

School Functioning (5 items)

- Summary scores:

Physical, Psychosocial and Total Health

- Validated in general paediatric population

# PedsQL – 3.0 Cerebral Palsy Module

- Newly developed
- **Scales** : Daily Activities (9 items)
  - School Activities (4 items)
  - Movement and Balance (5 items)
  - Pain and Hurt (4 items)
  - Fatigue (4 items)
  - Eating Activities (5 items)
  - Speech and Communication (4 items)
- **Summary scores** calculated for each scale.
- Validated in general CP population

# Hypothesis

- **Upper limb BTX-A therapy** will have a positive effect on **HRQOL** in children with **hemiplegic CP** as measured by the **PedsQL 4.0 Generic Core Scales** and **3.0 Cerebral Palsy Module**

# Secondary Aims

- Determine the *correlations* between:
  1. *Parent Proxy* and *Child Self-report* scores
  2. *PedsQL* scores and *MUUL* (Melbourne Assessment of Unilateral Upper Limb Function)
    - quality of functional movement score

# Participants

## ■ Inclusion Criteria

- hemiplegic CP
- age 7y0m – 13y11m
- dynamic spasticity UL

## ■ Exclusion Criteria

- significant cognitive impairment
- unable to attend all assessments

# Setting

## ■ Recruitment

- Spasticity Management Clinic, PMH
- Cerebral Palsy Assoc of WA

## ■ Assessments

- Centre for Neuromuscular and Neurological Disorders, UWA, Perth

## ■ Ethical Approval

- PMH, CPWA, UWA Ethics Committees

# Design

Treatment Group (12)	Control Group (11)
<b><i>One series UL BTX-A</i></b> <i>- Muscle selection individualised</i>	<b><i>No UL BTX-A</i></b>
+/- LL BTX-A	+/- LL BTX-A
Community OT and Physio	Community OT and Physio

# Assessments

- Baseline, 1, 3, 6 months
- PedsQL
  - 4.0 Generic Core Scales & 3.0 CP Module
    - Child Self-report
    - Parent Proxy
- MUUL : reach, grasp, release, manipulation
  - videotaped, blinded assessor.

# Statistical Analysis – group

- SPSS
- Student t tests
  - group comparison
- Linear mixed modelling :
  - covariates - age, gender, treatment group, day, day\*day

# Statistical analysis - correlations

- SPSS

- **Spearman correlation coefficients:**

  - <0.40 poor to fair agreement

  - 0.41 to 0.60 moderate agreement

  - 0.61 to 0.80 good agreement

  - 0.81 to 1.00 excellent agreement

- Statistical significance  $p < 0.05$

# Results

- **Follow-up attendance 97%**
- 2 participants attended 3 of 4 assessments.  
Remaining participants attended all assessments.
- 0 lost to follow up

# Group Comparison

	Group	Mean	Std Dev	Sig. (2 sided p value)
<b>Gender</b> M1/ F2	Treatment	0.56	0.49	0.578
	Control	0.38	0.48	
<b>Age</b> (years)	Treatment	10.72	1.81	0.823
	Control	10.55	2.16	
<b>MUUL</b>	Treatment	71.54	13.84	0.597
	Control	71.67	12.16	

# Treatment Group Analysis

## Generic 4.0 Core Scales (*p values*)

<b>Scale</b>	<b>Child Self-Report</b>	<b>Parent Proxy</b>
Physical Functioning	0.702	0.048
Psychosocial Functioning	0.711	0.490
Total Functioning	0.892	0.303

# Treatment Group Analysis

## 3.0 Cerebral Palsy Module (*p values*)

<b>Scale</b>	<b>Child Self-Report</b>	<b>Parent Proxy</b>
Daily Activities	0.806	0.696
School Activities	0.860	0.893
Movement& Balance	0.799	0.915
Pain & Hurt	0.685	0.477
Fatigue	0.660	0.954
Eating Activities	0.935	0.690
Speech/Communic	0.250	0.296

# Linear Trends

## 4.0 Generic Core Scales (*p values*)

<b>Scale</b>	<b>Child Self-Report</b>	<b>Parent Proxy</b>
Physical Functioning	0.008	0.065
Psychosocial Functioning	0.049	0.180
Total Functioning	0.013	0.028

# Linear Trends

## 3.0 Cerebral Palsy Module (*p values*)

<b>Scale</b>	<b>Child Self-Report</b>	<b>Parent Proxy</b>
Daily Activities	0.011	0.124
School Activities	0.077	0.099
Movement&Balance	0.054	0.755
Pain & Hurt	0.030	0.034
Fatigue	0.116	0.391
Eating Activities	0.539	0.374
Speech/Commun	0.506	0.874

## Correlations

### Child Self-Report: Parent Proxy

Agreement	Score (SCC)
<b><i>Good</i></b>	CP Daily Activities (0.67) CP Speech & Communication (0.62)
<b><i>Moderate</i></b>	CP Fatigue (0.58) Generic Total (0.53) CP Pain & Hurt (0.50) Generic Psychosocial (0.49) Generic Physical (0.45)

- *No significant correlation between CP Eating Activities and Movement*

## Correlations

### HRQOL: Function (MUUL)

Agreement	Score (SCC)
<b><i>Moderate</i></b>	Generic Parent Psychosocial (0.53) Generic Parent Total (0.52) CP Child Daily Activities (0.41) Generic Parent Physical (0.37)
<i>No significant correlation between other scores and MUUL</i>	

# Limitations / Considerations

- Study size
- Generalisability
- Responsiveness of PedsQL:  
Ability of PedsQL 4.0 **Generic** Core Scales and 3.0 **CP** Module to detect change in HRQOL over time in highly functional children with CP (GMFCS 1 and 2)

# Conclusion

- **Primary :**

**Upper limb BTX-A therapy** has minimal statistically significant effect on **HRQOL** in children with **hemiplegic CP** as measured with the **PedsQL 4.0 Generic Core Scales** and the **3.0 CP Module**

# Conclusion

- Secondary:

- **Child self-report scores** should be collected when assessing child **HRQOL** in addition to parent proxy reports.

- **UL functional ability** needs to be assessed independently to **HRQOL** in children with hemiplegic CP

# Recommendations

- Larger study in broader CP population
- Development of CP specific HRQOL tools which are responsive to small changes in the higher functioning cohort (GMFCS 1 and 2).

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