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A randomised trial of Botulinum Toxin A (BTX-A) combined with hip bracing in children with marked spastic cerebral palsy: Impact on functional outcomes

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Objectives: Following presentation of the delay of progression to surgery outcomes the present study aims to determine whether BTX-A combined with a variable hip abduction orthosis improves gross motor function in children with marked spasticity and hip displacement.

Design: A 3 year prospective randomised multicentre trial with concealed allocation to either BTX-A and bracing and/ or observation.

Methods: Ninety children with bilateral spastic cerebral palsy with hips at risk (MP > 15 < 40%) were entered. After randomisation children were allocated to receive either intramuscular BTX-A every six months of 16U kg/bodyweight (Botox, Allergan) to both adductors and hamstrings with the addition of 8 hours use per day of the variable hip abduction orthosis (SWASH, CAMP Ltd) and /or observation. In the observation group no concomitant hip bracing was undertaken, though physiotherapy and specialised seating were monitored. When MP > 40 % and /or the AI > 27° they exceeded study criteria and were presented for independent (blinded) analysis by a surgeon to determine progression to surgery. Changes in function were measured using the Gross Motor Function Measure (GMFM 88) measure at baseline and 12 monthly intervals until study completion or progression to surgery. Data for functional outcomes was analysed blinded to group allocation (BTX-A and control) using generalised estimating equations (GEE). Secondary analysis analysed annual GMFM change by Gross Motor Function Classification System (GMFCS) level.

Results: *Post hoc* analysis demonstrated no differences between the groups at baseline (Est. mean diff. 1.6; 95%CI -1.7, 4.9; $p=0.4$). Over the 3 yr f/u there was a significant annual improvement in GMFM of 4.6 % per year for the BTX-A group (95%CI 3.5.7; $p=0.001$). Between group differences demonstrated an annual improvement for the control group that was 1.2% *less* per annum than the BTX-A group (95%CI -2.8, 0.4; $p=0.13$) however these group differences were not significant. Adjusting for GMFCS level at baseline for Level II& III subjects the control group had a 2.6% *greater* annual change in GMFM ($p=0.02$) but more of these children progressed to surgery; in Level IV the BTX-A group had a 1.9% *greater* annual change ($p=0.3$, NS) and Level V there were a 1.5 % annual change in GMFM for *both* groups ($p=0.003$). Using the log rank test for comparing progression to surgery between the groups there was a statistically significant treatment effect ($p=0.004$) for the BTX-A and brace group.

Conclusion(s): There was a positive delay in the progression to surgery for BTX-A and hip bracing in the conservative management of hip displacement compared to standard conservative management. Both groups improved in gross motor function over time, however there was a greater annual improvement for the BTX-A treated group. There were no significant differences between the groups according to level of severity.

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