Effectiveness and safety assessment of IncobotulinumtoxinA (XEOMIN®) injections in the lower-limb muscles of young, low-weight children with cerebral palsy

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Introduction

Cerebral palsy (CP) is a complex cerebral disorder with final expression in different etiological disorders, not only affecting motor activity but also often associated with other disturbances involving sensation, perception, communication and behaviour (1). Spasticity is frequently found in CP and it is characterized by a muscular resistance to stretching or by an excessive or involuntary muscle activity. Focal treatment of CP is mainly represented by botulinum neurotoxin (BoNT) that directly treats the symptomatic muscles. Long-term treatment of children with CP requires avoidance of neutralizing antibodies that have been reported to cause an inadequate response (2). IncobotulinumtoxinA is a BoNT formulation free from complexing proteins (3). One of the supposed advantages that incobotulinumtoxinA may have over other botulinum toxin formulations is its lower antigenic potential due to the lower protein content.

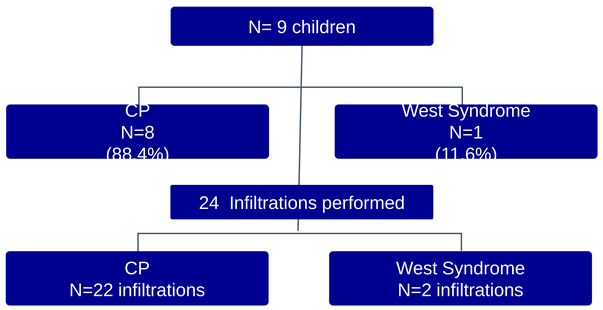
Objective

The objective of this work is to provide our experience on the tolerability and effectiveness of IncobotulinumtoxinA (Xeomin®), for treatment of lower-limb spasticity in low-weight children with CP or other motor disorders.

Methods

Nine children (2.5–6 years) with CP (n=8) or West Syndrome (n=1), with low weight (mean 17.7, standard deviation [SD] 4.8 kg) and spastic hemiplegia or diplegia were treated with IncobotulinumtoxinA (Xeomin®). All injections were performed by the same practitioner with ultrasound guidance, in 43% of cases under general anaesthesia. Assessments performed before and 3 months after treatment included the modified Ashworth Scale (MAS) and subjective global impressions of change rated by the physician and parent/caregiver. Parents/caregivers were asked 3 months after treatment about occurrence of adverse effects.

Figure 1: Disposition of patients and infiltrations performed.



Diagnosis	N
Diplegia	5
Left hemiplegia	1
CP due to prematurity	1
Dystonic CP	1
West Syndrome	1

Results

The mean (SD) dose of incobotulinumtoxinA administered was 212.9 (62.4) U, corresponding to a mean dose of 12U/kg body weight (maximum total dose 300U). Muscles injected in children with CP and data on the infiltrations to the child with West Syndrome are shown in Tables 1 and 2. Three months after treatment, a positive response was reported for 77% of the children, with objective (≥1 point improvement in MAS score) and subjective (global impression of change rated by the physician and parent/caregiver) improvements. No adverse effects were reported.

Table 1: Muscles injected in children with CP.

Injected Muscles	Total (I=22 / N=8)
Gastrocnemius	11 (50.0%) / 7 (87.5%)
Tibialis posterior	12 (54.5%) / 6 (75.0%)
Adductors	9 (40.9%) / 6 (75.0%)
Psoas	9 (40.9%) / 6 (75.0%)
Rectus femoris	6 (27.3%) / 3 (37.5%)
Soleus	5 (22.7%) / 3 (37.5%)
Gracilis	2 (9.1%) / 2 (25.0%)

Table 2: Data of infiltrations performed in the child with West Syndrome

Nº Infilt.	Age (years)	Weight (kg)	Total Dose	Muscles	Subjective Results	Objective results
1	2.6	13	200	Tibialis posterior and gastrocnemius	Improve	Improve
2	3.2	13	75	Triceps and pronator	Improve	Improve

Conclusions

BoNT is a powerful neurotoxin that has an established place in the treatment of spasticity in CP. Results suggest that incobotulinumtoxinA is an effective and well-tolerated therapeutic option for lower-limb spasticity in young, low-weight children with CP and other motor disorders. Further studies in a larger population are needed to confirm safety and effectiveness in different muscles and after repeated injections.

References

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