# EFFICACY AND SAFETY OF INCOBOTULINUMTOXINA (XEOMIN®) IN THE TREATMENT OF SEVERE MUSCLE SPASTICITY FOLLOWING TRAUMATIC BRAIN INJURY: A CASE REPORT

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## INTRODUCTION AND OBJECTIVES

In case of paraplegia, botulinum toxin type A (BoNT-A) injection is the gold standard therapy to reduce the muscles' overactivity in case of focal spasticity. This treatment option shows low prevalence of complications, reversibility and high efficacy in reducing spastic hypertonia (1). Severe traumatic brain injury (TBI) can result in spasticity that reduces function and quality of life and requires an individualized botulinum toxin treatment approach. The possibility of using incobotulinumtoxinA a highly purified BoNT-A treatment free from complexing proteins and, thus, associated with a relatively low risk of immunogenicity (2) may represent a therapeutic advantage for a long-term treatment and for the use of flexible and / or high doses. We report a case study of the efficacy and safety of IncobotulinumtoxinA (Xeomin) in a 28-year-old male with severe multi-level spasticity including equinovarus deformity of both ankles (60° plantar flexion, modified Ashworth Scale [MAS] score of 4) following TBI and subarachnoid hemorrhage in November 2015.

## METHODS

Due to the severity of spasticity and functional impairment, 500U IncobotulinumtoxinA were injected into the flexor muscles of the ankles (gastrocnemius medialis/lateralis, soleus, tibialis anterior/posterior, flexor hallucis longus and flexor digitorum longus) every 4 weeks into alternating sides at each session. The patient received 6 sessions over 5 months (22 Nov 2015 – 28 Apr 2016). The muscles and doses injected at each session are shown in Table 1. Clinical assessments were performed at baseline and 4 weeks after each session, including MAS (severity of spasticity grading the resistance of a relaxed limb to rapid passive stretch on a scale from 0 to 5) and functional assessment using Glasgow Outcome Scale (GOS, 5 levels: good recovery, moderate disability, severe disability, vegetative state and death) and Barthel Scale (BS, ranging from 0 to 100, with 0 indicating a totally dependent, bedridden state and 100 indicating that the patient is fully independent).

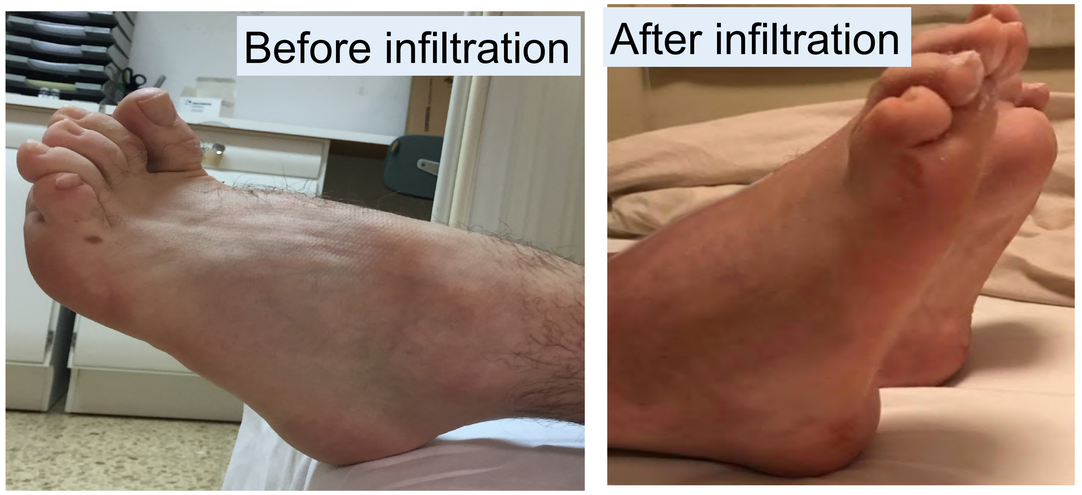


**TABLE 1:** Individual doses of IncobotulinumtoxinA injected in single muscles at each injection session

| Date | Total Units | Upper Limb (UL) | | Left Lower Limb | | | | | Right Lower Limb | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Biceps | Flexor Digitorum Profundus | Triceps surae | Tibialis anterior | Tibialis posterior | Fiexor hallucis longus | Flexor digitorum longus | Triceps surae | Tibialis anterior | Tibialis posterior | Fiexor hallucis longus | Flexor digitorum longus |
| 22.11.15 | 500 | 100 | - | 100 | | 100 | - | | 100 | 100 | - | - | - |
| 09.12.15 | 500 | 50 | 50 | 100 | | 100 | - | | 100 | 100 | - | - | - |
| 01.02.16 | 500 | - | - | 100 | 50 | 50 | 25 | 25 | 100 | 50 | 50 | 25 | 25 |
| 22.02.16 | 500 | - | - | 150 | 50 | - | - | 50 | 150 | 50 | - | - | 50 |
| 30.03.16 | 500 | - | - | - | - | - | - | - | 300 | 100 | 50 | - | 50 |
| 28.04.16 | 500 | - | - | 300 | - | 150 | - | 25 | - | - | - | - | - |
| On 28.04.16 25 U were also injected in dorsal and palmar interossei muscles | | | | | | | | | | | | | |

## RESULTS

Four weeks after IncobotulinumtoxinA injections, left and right plantar flexor MAS scores improved to 2.0 and the passive range of motion of left and right ankle dorsiflexion improved to 30°. GOS score improved from 3 to 5 and BS scores improved from 0 to 65; the patient began to stand and walk independently with a splint. Five months after severe TBI, intensive rehabilitation and frequent incobotulinumtoxinA injections markedly improved spasticity allowing the patient to walk with improved gait velocity, stride length, distance and swing symmetry. There were no local or systemic adverse effects.

## CONCLUSIONS

Our experience with this case of paraplegia involving several lower limb muscles is that IncobotulinumtoxinA injections is a well tolerated and effective procedure to resolve localized severe and disabling spasticity of the ankle and to prevent secondary complications. This case was well managed with IncobotulinumtoxinA using a flexible individualised treatment with higher doses and/or injection schedules that were tailored to the clinical needs of the patient, to improve active function and associated clinical symptoms (including pain, rigidity, disability and discomfort sensations) following TBI.

## REFERENCES

1. Santamato, A. Safety and efficacy of incobotulinumtoxinA as a potential treatment for poststroke spasticity. Neuropsychiatric Disease and Treatment 2016: 12, 251-263
2. Frevert J. Content of botulinum neurotoxin in Botox®/Vistabel®, Dysport® /Azzalure®, and Xeomin®/Bocouture®. *Drugs R D.* 2010; 10(2): 67–73