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Incobotulinumtoxin A (Xeomin®) injected with flexible intervals is a well-tolerated long-term treatment of cervical dystonia

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Background. — Long-term management of cervical dystonia (CD) involves repeated botulinum toxin injections at around 3-month intervals. Many patients and physicians may prefer shorter intervals but it is assumed that this might increase the risk of adverse events (AEs) and neutralizing antibody formation. We analyzed the clinical need and safety of flexible injection intervals with Incobotulinumtoxin A (Xeomin®, NT 201), a purified botulinum toxin type A free from accessory (complexing) proteins.

Methods. — Post-hoc analysis was carried out using data from a randomized, double-blind, placebo-controlled phase 3 study with a randomized, double-blind extension period. Subjects with CD (pretreated or botulinum toxin treatment naïve) could receive ≤ 6 Incobotulinumtoxin A treatments with fixed doses (120 or 240 U) but flexible intervals (≥ 6 weeks). Re injection occurred when subjects and physicians agreed on the need and subjects had a Toronto Western Spasmodic Torticollis Rating Scale total score of ≥ 20. Standard safety assessments were performed throughout.

Results. — Two hundred and fourteen subjects entered the extension period (120 U dose group, n = 103; 240 U dose group, n = 111). In total, 821 injections were included in this analysis: 369 (44.9%) given at 6–11 week intervals and 452 (55.1%) at > 12–20 weeks intervals. Frequency and severity of AEs were similar, irrespective of injection intervals (< 12 weeks versus ≥ 12 weeks), with no cumulative effects of repeated treatment. As would be expected in CD, the most frequent AEs were muscle weakness, neck pain, and injection-site pain.

Discussion. — Incobotulinumtoxin A, injected at flexible intervals according to subjects’ clinical needs, is effective and well tolerated in the long-term management of CD.

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Reliability of the goniometric measurement of ankle dorsiflexion in hemiparetic patients

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Introduction. — The equinus foot deformity is common in hemiparetic patients. Although widely used, the reproducibility of goniometric measurement of ankle dorsiflexion is little studied and variable. The objective was to evaluate the intra/inter-rater-reliability of this measure, and to evaluate a new method of goniometric measurement of ankle dorsiflexion in hemiparetic patients.

Methods. — Prospective, monocentric study; all hemiparetic patients due to a recent brain injury, hospitalized during the study period were included. Goniometric measurements of ankle dorsiflexion were performed on both healthy and hemiplegic sides, by four judges, and repeated a week later. Landmarks were either free (corresponding to the evaluators’ usual practice) or imposed. The conventional method evaluated the equinus on the hemiparetic side. The S. Index was defined as the difference between the dorsiflexion on the hemiparetic side and conventional method evaluated the equinus on the hemiparetic side. The S. Index was defined as the difference between the dorsiflexion on the hemiparetic side and conventional method evaluated the equinus on the hemiparetic side. The S. Index was defined as the difference between the dorsiflexion on the hemiparetic side and conventional method evaluated the equinus on the hemiparetic side.

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Results. — Nineteen patients with chronic hemiparesis (45 ± 16 years) participated. The spasticity grade and angle (XV1–XV3) of triceps surae (knee extended) and the angle of weakness (XV1–X) of dorsiflexion were measured using the step-wise assessment of spastic paresis, including the Tardieu scale [2,3]. Each subject performed a 10-meter barefoot walking test (seated start and arrival) at preferred and maximal speed. Spatial-temporal parameters were quantified: speed, step length and cadence. We explored correlations between spasticity and weakness parameters at the ankle and gait spatial-temporal parameters.

Results. — At preferred speed: speed, 0.69 ± 0.25 m/s; step length, 0.51 ± 0.12 m; cadence, 1.33 ± 0.31step/s. At fast speed: speed, 1.08 ± 0.40 m/s; step length, 0.55 ± 0.15 m; cadence, 1.91 ± 0.39step/s. In the paretic ankle: triceps surae spasticity grade, 2.2 ± 0.8; spasticity angle, 13.7 ± 6.5°; dorsiflexion angle of weakness, 13.2 ± 9.3°. At preferred speed, the angle of weakness was negatively correlated with speed (r = −0.48, P = 0.039), step length (r = −0.55, P = 0.014), and at fast speed, with speed (r = −0.56, P = 0.012), step length (r = −0.57, P = 0.010) and cadence (r = −0.47, P = 0.040).

Conclusions. — In chronic hemiparesis, ambulation (at preferred and fast speed), is correlated at the ankle with the combination of tibialis anterior paresis and triceps surae cocontraction rather than with triceps surae spasticity.

References

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Satisfaction with botulinum toxin treatment in poststroke spasticity: Results from a cross-sectional physician survey