HRV has been widely used to evaluate the control exerted by the autonomic nervous system on cardiovascular activities, including vagal and sympathetic components. The aim of this study was to evaluate changes in HRV induced by BoNT-A (NT-201) injection in spastic stroke patients.

Methods. – Eleven stroke survivors with spastic hemiplegia were injected with IncobotulinumtoxinA (100 units:2 mL of 0.9% NaCl), with doses > 600 UI (maximal dose < 12 UI/Kg). They received two ECG registrations of 30 min each, the first 24 h before injection and the second 10 days after. Linear and non-linear HRV variables were obtained with HRV analysis software.

Results. – None of the variable considered for time, frequency domain and non-linear domain suffer significant changes after BoNT-A injection.

Conclusions. – High doses of BoNT-A do not influence cardiac autonomic drive. Moreover, no clinical adverse events of any kind occurred in anyone of our patients after NT-201 injection.

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P211-e

Incobotulinum booster injections in patients with spasticity and dystonia after stroke

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Keywords: Spasticity; Stroke; Dystonia; Incobotulinum tox A; Booster injection

Background. – Previous results in patients injected with abobotulinum toxin A and onabotulinum toxin A have shown that injection intervals shorter than 2 months may increase the risk for neutralising antibody formation and treatment non-response. As a result, for the last 10 years, we have adopted longer intervals to treat patients with spasticity and/or dystonia secondary to stroke. It has been shown that incobotulinum tox A does not induce neutralising antibodies.

Observations. – Ten patients with spasticity and/or dystonia due to stroke underwent a booster injection one month after the first injection. The clinical results were compared to those previously obtained in the same 10 patients using a single injection. Secondary dystonia was evaluated using the Unified Dystonia Rating Scale (UDRS), while spasticity was evaluated according to the Modified Ashworth Scale (MAS).

Results. – They showed that the booster injection protocol induced an improvement in 8 subjects. In the remaining 2 subjects, we did not find any difference between the results obtained using the single and the booster injection protocols.

Conclusions. – The use of a booster injection improve the clinical outcome in patients with spasticity and/or dystonia after stroke, allowing an optimal treatment of those muscles that poorly responded to the first injection.

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P212-e

SPACE, interim analyses of an international, non-interventional study of botulinum toxin treatment for spasticity

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Keywords: Botulinum toxin type A; Spasticity; IncobotulinumtoxinA; OnabotulinumtoxinA; AbobotulinumtoxinA

Background. – SPACE, an international, non-interventional study, is collecting effectiveness, safety and quality of life (QoL) data on botulinum toxin type A (BoNT-A) treatment for spasticity in a routine practice setting. Here, we present interim analyses of the first treatment cycle.

Methods. – BoNT treatment-naïve adults with spasticity of any aetiology were followed for up to 2 years. Data collected include global assessments of efficacy (patient-rated [PGAE] and investigator-rated [IGAE]) and investigator global assessment of tolerability (IGAT). Global assessments were made at the end of the first treatment cycle and scored from 1 = very good to 4 = poor. PGAE/IGAE responders were defined as patients with scores ≤ 3 = moderate.

Results. – The interim analyses include 648 patients (61.9% male, mean [standard deviation] age 54.8 [15.6] years) who received 1 treatment cycle with incobotulinumtoxinA (n = 435), onabotulinumtoxinA (n = 138) or abobotulinumtoxinA (n = 75). Overall, 468/510 (91.8%) patients were PGAE responders and 476/500 (95.2%) patients were IGAE responders. IGAT was very good or good for 467/500 (93.4%) patients.

*Interim analyses – data were not yet available for all patients

Conclusions. – For patients with focal spasticity, their first-ever BoNT-A treatment cycle was efficacious and well tolerated. Longer-term data will assess the benefits of BoNT-A injections over multiple treatment cycles.

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P213-e

Efficacy of incobotulinum toxin A (Xeomin®) in the treatment of dynamic equinus foot in children with hemiplegic cerebral palsy

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Keywords: Cerebral palsy; Spasticity; Incobotulinum tox A

Background. – Previous studies have shown the efficacy of botulinum toxin type A (BoNT-A) in the management of ambulant individuals with cerebral palsy (CP). We evaluated the efficacy of incobotulinum toxin A (Xeomin®) injections in children with dynamic equinus affected by hemiplegic CP in polycentric study.

Methods. – The efficacy of treatment was tested in 30 children aged from 2 to 18 years with spasticity more than 2 at Modified Ashworth Scale, injections were performed in calf muscles up to 200U, with electromyographic guidance. The treatment efficacy was evaluated with the Modified Ashworth Scale, Tardieu Scale, Active and Passive Range of motion and Walking test on 10 m. Clinical data were collected at time 0 and at 1, 3 and 6 months after the injections.

Results. – Preliminary data showed good efficacy and tolerability of treatment spasticity with botulinum toxin A in children.

Conclusions. – Incobotulinum toxin A seems to be as effective as other type A botulinum toxins. The absence of proteins could be an advantage in the paediatric population requiring repeated treatments over time.

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P214-e

TOWER: Design of an open-label incobotulinumtoxinA dose-titration study (up to 800 U) in lower and upper limb spasticity

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Keywords: Spasticity; Botulinum toxin type A; Spasticity; IncobotulinumtoxinA; OnabotulinumtoxinA; AbobotulinumtoxinA

Background. – TOWER, an international, non-interventional study, is collecting effectiveness, safety and quality of life (QoL) data on botulinum toxin type A (BoNT-A) treatment for spasticity in a routine practice setting. Here, we present interim analyses of the first treatment cycle.

Methods. – BoNT treatment-naïve adults with spasticity of any aetiology were followed for up to 2 years. Data collected include global assessments of efficacy (patient-rated [PGAE] and investigator-rated [IGAE]) and investigator global assessment of tolerability (IGAT). Global assessments were made at the end of the first treatment cycle and scored from 1 = very good to 4 = poor. PGAE/IGAE responders were defined as patients with scores ≤ 3 = moderate.

Results. – The interim analyses include 648 patients (61.9% male, mean [standard deviation] age 54.8 [15.6] years) who received 1 treatment cycle with incobotulinumtoxinA (n = 435), onabotulinumtoxinA (n = 138) or abobotulinumtoxinA (n = 75). Overall, 468/510 (91.8%) patients were PGAE responders and 476/500 (95.2%) patients were IGAE responders. IGAT was very good or good for 467/500 (93.4%) patients.

*Interim analyses – data were not yet available for all patients

Conclusions. – For patients with focal spasticity, their first-ever BoNT-A treatment cycle was efficacious and well tolerated. Longer-term data will assess the benefits of BoNT-A injections over multiple treatment cycles.

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elbow flexor spastic dystonia and improve functionality.

Results.– Maximal range of passive motion against the elbow flexors (XV1) was monitored by two examiners. Once monthly we monitored spasticity with the Tardieu Scale and active motion range (A) from 78° to 164° (+14°), angle of catch (XV3) from 92° to 116° (+24°) and active motion range (A) from 78° to 92° (+14°). Regarding active limb function, score improved by 1/10 point for three tasks involving active elbow extension.

Conclusion.– Upper limb loading may be of benefit in hemiparesis to reduce spasticity in hereditary spastic paraparesis. Walking ability of these persons is still a big question depending on the degree of paralysis and the severity of the disease.

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P215-e

Upper limb loading in elbow flexor spastic dystonia

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Keywords: Spasticity; Spastic dystonia; Limb loading; Rehabilitation; Stroke; Upper limb function

Background.– Studies have demonstrated reduction of spastic dystonia with sustained stretch. The aim of the present work was to evaluate the effects of upper limb wrist-worn loading in a patient with elbow flexor spastic dystonia.

Methods.– A 53-year-old male with left spastic hemiparesis secondary to a cerebral infarct 2 years prior has benefited from a 3-month rehabilitation program, including botulinum toxin injections at the Neurorehabilitation Day Hospital in Albert-Chenevier hospital, Créteil, France. Within this program the patient has worn a loaded wrist splint (1.5 kg) daily. Every day, he reported the total loading time together with any untoward effects in a diary. Once monthly we monitored spasticity with the Tardieu Scale and active arm function with the Modified Frenchay Scale using blinded review by two examiners.

Results.– Maximal range of passive motion against the elbow flexors (XV1) increased from 144° to 164° (+20°), angle of catch (XV3) from 92° to 116° (+24°) and active motion range (A) from 78° to 92° (+14°). Regarding active limb function, score improved by 1/10 point for three tasks involving active elbow extension.

Conclusion.– Upper limb loading may be of benefit in hemiparesis to reduce elbow flexor spastic dystonia and improve functionality.

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P216-e

Treatment of scoliosis with paraspinal injection of botulinum toxin in quadriplegic woman

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Keywords: Stroke; Paraspinal; Botulinum; Toxin

Background.– Type A botulinum toxin has been used in paraspinal muscles for several conditions like stiff-person syndrome, back pain in cerebral palsy, chronic low back pain, X-linked dystonia-parkinsonism.

Methods.– A 30-year-old woman developed a spastic quadriplegia with right side more involved, after a severe stroke at the age of 19. Although she was following a rehabilitation programme for several years, she only improved her ability to walk slowly for up to 30 steps unaided.

Results.– After treatment with type A botulinum toxin (Botox) for 6 years in limb muscles, during the last 2 years, she developed a scoliosis which interfered with her gait pattern. Right paraspinal thoracic muscles were injected, with botulinum toxin in 6 segments, using 20U in each site. This treatment was repeated 4 times each year. Patient improved posture in standing position and facilitated the gait pattern and velocity. She could walk more than 50 steps without assistance, without body shifting and with a faster gait speed.

Conclusions.– Administration of botulinum toxin A reduced the tone of paraspinal and improves significantly improvement of gait pattern in quadriplegic woman.

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P217-e

Hereditary spastic paraparesis and intrathecal baclofen

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Keywords: Hereditary spastic paraparesis; Intrathecal baclofen; Spasticity

Background.– Intrathecal baclofen has been used to treat lower limb spasticity in hereditary spastic paraparesis. Botulinum toxin type A has also been used for the same reason.

Methods.– We present three cases of women (aged 47, 58, and 59) with hereditary spastic paraparesis treated in our PRM department.

Results.– Patients were under intramuscular antispastic treatment with 400 U of type A botulinum toxin for two years period, in hip adductors, hamstrings and triceps surae. After 4, 8, 12, 16, 20 and 24 months of botulinum toxin, Modified Ashworth Scale showed improvement of spasticity not enough to improve the gait velocity, measured with 10 m walking test. Patients were referred to Neurosurgical department where they were treated with permanent intrathecal baclofen pump, after positive test of 50 μg baclofen intrathecally. MAS score was also improved but with not significant improvement in gait pattern. Daily living activities were improved.

Conclusions.– Both botulinum toxin and intrathecal baclofen can reduce spasticity in hereditary spastic paraparesis. Walking ability of these persons is still a big question depending on the degree of paralysis and the severity of the disease.

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P218-e

Botulinum toxin treatment using flexible intervals for cervical dystonia

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Keywords: Cervical dystonia; Botulinum toxin; Dose titration

Background.– TOWER is a prospective, Phase IV, dose titration clinical trial (NCT01603459) investigating the safety and efficacy of incobotulinumtoxinA (Xeomin®) in patients with spasticity, deemed to require doses higher than currently approved.

Methods.– Patients (18–80 years) with upper- and lower-limb spasticity of the same body side due to cerebral causes, deemed by the investigator to require total body doses up to 800U of incobotulinumtoxinA per injection cycle, will undergo 3 injection cycles (400, 600, and 800U incobotulinumtoxinA, respectively), each followed by 12- to 16-week observation periods with telephone contacts at 1 and 2 weeks and follow-up visits at 4, 8, and 12-16 weeks post-treatment. Co-primary outcome measures are adverse events and investigator’s global assessment of tolerability. Muscle tone (Ashworth Scale), Resistance to Passive Movement Scale, Functional Ambulation Classification scale, Goal Attainment Scale, Disability Assessment Scale, quality of life, antibody formation, and pulmonary function will also be assessed.

Results.– As of October 2013, patients (enrolment target 150) are being recruited at 33 sites throughout Europe, Canada and the USA.

Conclusions.– TOWER will provide important insights into the safety and efficacy of higher than currently recommended incobotulinumtoxinA doses in patients with multifocal upper- and lower-limb spasticity.

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