Physician characteristics in an international, non-interventional study of botulinum toxin formulations in treatment-naïve patients with spasticity (SPACE)

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

Background. – Botulinum toxin type A (BoNT-A) injections are a key treatment in the interdisciplinary management of patients with spasticity. Here, we present interim analyses of characteristics of physicians participating in the SPACE study.

Methods. – SPACE, an international, observational study of the safety and effectiveness of several BoNT-As, followed previously BoNT-naïve patients with spasticity for up to 2 years. Data regarding physicians’ speciality, medical experience, BoNT-A dosing preferences and treatment approaches were collected.

Results. – These interim analyses included 230 physicians from Europe (66.1%), Canada (6.1%), Mexico (4.8%) and Russia (5.7%). Most physicians were neurologists (50.9%) or physiatrists (36.5%). Treating physicians had a median 15 years’ experience in medical practice (range 1–36 years; experience with BoNT-A, 0–25 years [median 8.5 years]). Most physicians (60.9%) would inject higher BoNT-A doses if permitted by product labelling. For 48.9% of patients (317/648), the BoNT-A treatment decision was agreed by a multidisciplinary team.

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

Conclusions. – Data from SPACE will help to further define the role of BoNT-A as part of a multimodal management approach for focal spasticity and aid patients in this diverse population achieve individual treatment goals.

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Patients’ baseline characteristics in SPACE, an international, non-interventional study of botulinum toxin treatment for spasticity

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Background. – Botulinum toxin A (BoNT-A) injections are a key treatment for patients with spasticity. Here, we present interim analyses of patient baseline characteristics in SPACE, an international, non-interventional study of the safety and effectiveness of BoNT-A formulations.

Methods. – SPACE followed BoNT treatment-naïve patients with spasticity (any aetiology) for up to 2 years. Data collected included baseline disease characteristics and key treatment goals, as agreed by each patient and physician.

Results. – These interim analyses include 648 patients* (61.9% male, mean [standard deviation (SD)] age 54.8 [15.6] years). Causes of spasticity included stroke (66.4%), multiple sclerosis (9.7%) and brain injury (6.5%). Most patients (79.3%) were hemiplegic (diplegic, 11.7%; quadriplegic, 7.9%). Median time since the spasticity-causing event was 2.0 years (range 0–63 years). Many patients (57.4%) reported spasticity-related pain (mild, 20.1%; moderate, 28.1%; severe, 9.3%). The most common key treatment goals were “improvement in mobility” (20.5%), “improvement in dexterity and reaching” (15.7%) and “pain relief” (11.9%).

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

Conclusions. – Data from SPACE will help to further define the role of BoNT-A as part of a multimodal management approach for focal spasticity and aid patients in this diverse population achieve individual treatment goals.

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Treatment of multifocal spasticity with high-doses of incobotulinumtoxinA (Xeomin®) in stroke patients

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Keywords: Botulinum toxin type A; Muscle spasticity; Stroke

Background. – In adult, stroke patients maximal recommended dose of onabotulinumtoxinA is 600 UI, with reported generalised side-effects at 800 UI [1]. Doses up to 840 UI of IncobotulinumtoxinA have been reported in a case without side effects, but more precise data are lacking [2]. We report the use of high doses of incobotulinumtoxinA in a group of patients.

Methods. – Clinical records of 46 stroke survivors (19 females) with spastic hemiplegia treated with IncobotulinumtoxinA (100 UI:2 mL of 0.9% NaCl), with doses ≥ 500 UI (maximal dose < 14 UI/Kg) were reviewed. Muscles, dose for each muscle, Ashworth grade before and 1 month after treatment and side effects were recorded.

Results. – Mean incobotulinumtoxinA dose was 638.3 ± 106.9 UI. Mean Ashworth score at injected muscle was 3.39 ± 0.94 (median 3, IQR 3–5) before treatment and 1.22 ± 1.04 (median 1, IQR 0–5) after treatment. Twenty-three patients had ≥ 700 UI. Each patient had a mean of 9.65 muscles treated. No adverse events were noted in this group.

Conclusions. – In our retrospective analysis, incobotulinumtoxinA at high doses in multifocal treatment for spasticity showed to be effective and safe.

References

Heart rate variability (HRV) modifications in adult hemiplegic patients after botulinum toxin type A (NT-201) injection

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Keywords: Botulinum toxin type A; Stroke; Muscle spasticity; Heart rate variability (HRV)

Background. – In rodents, botulinum toxin type A (BoNT-A) is retrogradely transported to second-order neurons in the central nervous system (CNS). At present, time data in humans are missing.