

## "Abobotulinumtoxina (Dysport®): Doses Used to Treat Upper Limb Muscles of Adults with Spasticity Participating in a Phase III Randomized, Double-Blind Placebo- Controlled Study"

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### Abstract

**Introduction/Background:** In a Phase III, randomized, double-blind placebo-controlled study conducted in 34 sites from 9 countries, two doses of abobotulinumtoxinA (Dysport®) 500 and 1000 units (U) were shown to be efficacious on muscle tone for the treatment of hemiparetic adults post stroke or traumatic brain injury (TBI) with a favourable safety profile.<sup>1</sup> **Materials and Methods:** 243 patients received abobotulinumtoxinA 500 or 1000 U or placebo by intramuscular injection into their primary targeted muscle group (PTMG, selected from extrinsic finger flexors, wrist flexors and elbow flexors) and at least two other upper limb muscles, including shoulder muscles. Treatment was administered in a volume of 5.0 mL using electrostimulation. Doses administered to upper limb muscles are reported here. **Results:** For the abobotulinumtoxinA 500 U group, mean (SD) doses (U) administered in fingers flexors were: 93.5 (17.0) for flexor digitorum profundus (FDP), 95.4 (14.3) for flexor digitorum s...

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walking distance. *Methods:* Cross sectional study using thirty patient moderate and severe COPD (FEV1 30-80, FEV1/FVC < 70) aged 60-75 years were randomly assigned to the two groups, intervention and control. The intervention group received standard pulmonary rehabilitation, unsupported upper extremity exercise and treadmill exercise 3 times a week for 6 week, while control group received standard pulmonary rehabilitation and treadmill only. The main outcome measure are decrease ADL-time using Glittre ADL test and walking distance using 6 minutes walking test (MWT). *Results:* After 6 weeks, patients in the intervention group improved in the ability to do ADL with reduce ADL-time to do Glittre ADL test compared with those patients in the control group ( $p < 0.05$ ) also they could increase the walking distance from Minimal Important Difference. *Conclusion:* This study suggest that the combination upper and lower extremity exercise improve ability to do ADL and walking distance in elderly with moderate and severe COPD better than the lower extremity exercise only.

#### TA187

##### The Association between Anxiety at Time of Hospitalization and Future Falls among Older Adults Is Partly Mediated by Functional Decline

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*Objective:* Post acute hospitalization falls, among the elderly, were rarely discussed. The incidence of anxiety among the elderly is around 15%. The aim of this study is to test the association between anxiety at time of hospitalization and falls occurring within one-month post-discharge. And, to offer potential mechanism for this association. *Method:* One month prospective cohort study of 694 older adults in two Israeli medical centers. Falls, anxiety and peri hospitalization functional decline were assessed. *Results:* A total of N=87 (12.5%) participants reported at least one fall during the 30-day post-discharge period. Controlling for functional decline, cognitive status, chronic and acute illness severity, length of stay, pre-morbid mobility and sleep medication consumption; The odds of falls between discharge to 1-month follow-up were 1.73 (95% CI: 1.03-2.91) among patients with moderate to high anxiety. Among patients with functional decline by discharge, the odds of falls were 2.18 (95% CI: 1.12-4.22) for patients with moderate to high anxiety. When accounting for functional decline the relationship between falls and anxiety was reduced by 14% (from OR=2.19 to OR=1.91). *Conclusion:* Anxiety at time of hospitalization is associated with falls 30-days post discharge, controlling for several well known confounders. This relationship is partially mediated by functional decline. Identifying patients with anxiety for inclusion in targeted rehabilitation interventions may be an important component in fall prevention strategies.

## A.7.2 SPASTICITY MANAGEMENT

#### TA188

##### AbobotulinumtoxinA (Dysport®): Doses Used to Treat Upper Limb Muscles of Adults with Spasticity Participating in a Phase III Randomized, Double-Blind Placebo-Controlled Study

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bert, FR, <sup>7</sup>Weill Cornell Medical Center, New York, NY, US, <sup>8</sup>Institution of Russian Academy of Medical Sciences, Moscow, RU, <sup>9</sup>U.O. of Physical Medicine and Rehabilitation University Hospital, Catania, IT, <sup>10</sup>Ipsen Innovation, Les Ulis, <sup>11</sup>Hospital Albert Chenevier, Creteil, FR

*Introduction/Background:* In a Phase III, randomized, double-blind placebo-controlled study conducted in 34 sites from 9 countries, two doses of abobotulinumtoxinA (Dysport®) 500 and 1000 units (U) were shown to be efficacious on muscle tone for the treatment of hemiparetic adults post stroke or traumatic brain injury (TBI) with a favourable safety profile. *Materials and Methods:* 243 patients received abobotulinumtoxinA 500 or 1000 U or placebo by intramuscular injection into their primary targeted muscle group (PTMG, selected from extrinsic finger flexors, wrist flexors and elbow flexors) and at least two other upper limb muscles, including shoulder muscles. Treatment was administered in a volume of 5.0 mL using electrostimulation. Doses administered to upper limb muscles are reported here. *Results:* For the abobotulinumtoxinA 500 U group, mean (SD) doses (U) administered in fingers flexors were: 93.5 (17.0) for flexor digitorum profundus (FDP), 95.4 (14.3) for flexor digitorum superficialis (FDS) and 76.9 (26.8) for other finger flexors (flexor pollicis longus, adductor pollicis); in wrist flexors: 92.2 (18.1) for flexor carpi radialis (FCR) and 89.9 (25.7) for flexor carpi ulnaris (FCU); in elbow flexors: 88.3 (28.5) for brachioradialis, 148.5 (60.2) for brachialis and 108.6 (49.5) for other elbow muscles (biceps brachii, pronator teres) and 122.2 (44.1) in shoulder muscles (triceps brachii, pectoralis major, subscapularis, latissimus dorsi). For the abobotulinumtoxinA 1000 U group, doses administered were 195.5 (25.9) for FDP, 196.8 (28.4) for FDS, 157.0 (53.3) for other finger flexors, 178.1 (45.5) for FCR, 171.2 (45.2) for FCU, 172.1 (44.8) for brachioradialis, 321.4 (103.2) for brachialis, 216.5 (92.2) for other elbow muscles and 300.0 (129.1) in shoulder muscles. *Conclusion:* In this Phase III worldwide study in hemiparetic patients with upper limb spasticity post stroke/TBI, mean doses administered were 76.9–196.8 U for muscles in the finger flexors, 89.9–178.1 U for muscles in wrist flexors, 88.3–321.4 U for muscles in the elbow flexors and 122.2–300.0 U in shoulder muscles. Total dose administered (in the PTMG and at least 2 upper limb muscles) was 500 or 1000 U, which was previously shown to improve muscle tone in this patient population. *Reference:* Gracies JM, et al. WCNR 2014; abstract OP-144.

#### TA189

##### Long Term Improvement of Facial Function after a Combined Therapy with Botulinum Toxin A Injections and Mirror Biofeedback Rehabilitation

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*Background:* In the last twenty-five years several studies have demonstrated the efficacy of onabotulinumtoxinA (BoNT-A) injections in reducing facial synkinesis. Another common therapeutic option that has shown an important role in both the prevention and the treatment of facial synkinesis is facial neuromuscular retraining with mirror biofeedback (BFB). Despite the great number of studies about the efficacy of BoNT-A or BFB separately, in the literature there is a paucity of studies about the long-term effects on facial function of the combined therapy with repeated BoNT-A injections in association with BFB rehabilitation. *Aim:* to explore the presence of an acquired improvement of the facial function out of the pharmacological effect of BoNT-A in subjects with established facial palsy, after repeated sessions of BoNT-A injections combined with mirror biofeedback rehabilitation. *Setting:* Outpatient Clinic of Physical Medicine and Rehabilitation Unit, Fondazione IRCCS Policlinico San Matteo, Pavia, Italy. *Population:* 27 consecutive patients (22 females; mean age 45 ± 16 years) with an established facial palsy were treated for facial synkinesis in association with mirror biofeedback exercises at home. A minimum of three sessions