ences occurred for elbow, wrist and finger flexor spasticity, 3–6 weeks and 9–12 weeks after treatment. No improvement in weighted mean difference was observed in the trial of BoNT-B. Meta-analysis of the number of patients with reduction in Ashworth scores favored BoNT-A compared to placebo; similar data were not available for BoNT-B. BoNT was generally well tolerated.

The results of this study indicate that BoNT-A is safe and effective in reducing muscle hypertonia due to spasticity in upper limb joints. Insufficient data were available to assess the efficacy and tolerability of BoNT- B in spasticity.

Keywords: Spasticity; Botulinum toxin; Stroke
10.1016/j.toxicon.2008.04.068

67. A shot of myobloc: An answer to 25-year battle with Tics?

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Objective: To discuss the use, safety, and efficacy of Myobloc in Tics associated with pruritus.

Introduction: Tics are voluntary movements in response to an urge. Although rare, complaints of a "horrible" sensation, similar to an "itch", which always preceded the tic movements have been described. This sensation would thus be viewed as a trigger for the movements.

Method: Case report.

Result: The patient with annoying left scapular itch (pruritus) for more than 25 years describes her symptoms as very irritating, embarrassing, and distracting. Scratching does not alleviate the sensation but she receives transient relief whenever she pulls her left platysma, lower mouth, and trapezius. She concluded that the itch is similar to an irresistable urge to move her body. And although the movements are voluntary, attempts to suppress the movements usually result in a stronger itch and urge to move.

Prior to her consultation at our department, she had an extensive evaluation by a dermatologist and a rheumatologist. After a discussion, she opted for off-label trial of myobloc rather than oral medication. Myobloc was administered to the left scapularis, platysma, and trapezius. She reported at least 50% improvement in both sensation and movement at week 1 that lasted for 12 weeks without adverse effect.

Conclusion: This suggests that Myobloc may potentially be used as an antipruritic.

Keywords: Tics; Itch
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68. Neurobloc®/myobloc®: Unique features and findings

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The commercial availability of purified botulinum toxin type B (BoNT-B–NeuroBloc®/Myobloc®) adds a new and valuable weapon to our arsenal for the treatment of movement disorders and potentially pain. While BoNT-A and BoNT-B share many features, such as remarkable potency and high affinity for acetylcholine (ACh) neurons, they are antigenically distinct, each enters neurons through unique acceptor sites and cleaves different target proteins on the vesicle docking complex. NeuroBloc® was rationally developed and incorporates many key features not found in earlier toxins, including a non-lyophilized liquid formulation, stability at room temperature for 8 h and the use of a lower pH designed specifically to keep the toxin in complex and at a uniform molecular weight during the injection process. NeuroBloc® was also uniquely evaluated in an extensive series of preclinical studies that directly measured induced changes in the compound muscle action potential in non-human primates. These studies explored the closest feasible model to humans and provided an opportunity to compare the effects of BoNT-A and BoNT-B injected at doses producing equivalent paresis in contralateral muscles of the same preparation. These findings will be presented and discussed with regard to the pattern of change within a muscle, the comparative spread of the effects of the toxins to nearby and remote non-injected muscles and the duration of action of each serotype. Finally, the preclinical data will be discussed in relation to 'safety', the apparent affinity of BoNT-B to autonomic ACh neurons and the recovery of function in recent clinical studies.

Keywords: Botulinum toxin type B; Characteristics; Preclinical; Clinical
10.1016/j.toxicon.2008.04.070

69. Clinical safety of NT 201 (Xeomin®): A meta-analysis

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NT 201 (Xeomin®), a new formulation of botulinum neurotoxin type A, is free from complexing proteins. NT 201 has not been associated with immunogenicity in animal models. Analyses were performed on the pooled data from all subjects in 6 controlled clinical trials (blepharospasm, cervical dystonia, and upper limb spasticity). The pooled analyses include 539 NT 201 (Xeomin®), 442 BTXCo (Botox®), and 75 placebo subjects. Additionally, the data of patients treated with NT 201 post-launch have also been evaluated. In the randomized, controlled, double-blind studies NT 201 and BTXCo have been used with a conversion factor of 1:1, producing a comparable clinical efficacy. In the NT 201 group 26.7%, in the BTXCo group 26.0% and in the placebo group 22.7% of patients reported at least an adverse event (AE). The differences in individual AEs between the two botulinum formulations are only minor. The analysis of the 29,000 patients treated post-launch demonstrates that there is no fatal outcome with a causal relationship to NT 201. No new safety concerns have been identified from the spontaneous reports since the market introduction in 2005. All adverse reactions reported were either already known and/or were considered unlikely to be related to

NT 201 by the treating physician. In the meta-analysis of 6 NT 201 trials as well as approximately 29,000 post-launch patients, NT 201 has demonstrated a favorable risk–benefit profile.

Keyword: Xeomin
10.1016/j.toxicon.2008.04.071

70. Botulinum Toxin Type B clinical safety in cervical dystonia following up to 4 years of treatment

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Objective: Summarize the Botulinum Toxin Type B (BoNT-B) clinical adverse event (AE) data in cervical dystonia (CD).

Background: 759 unique patients (pt) received BoNT-B in 1 comparator and 4 placebo-controlled trials (CT) and 3 open-label trials (OLT). Doses ranged from 400 to 25 K Units (U).

Methods: AE data were pooled and tabulated.

Results: AE data represent 1432 pt-years; 5727 injections. Most pts were female (61%) and white (97%); mean age was 52.5 yrs. The median dose in most open-label sessions was 15 K U. In 2 long-term OLTs ($n = 557$) 22% of pts received doses from >20 K to 25 K U. Treatment-related AEs (TRAE) occurred in 160 (51%) pts in CT and 524 (76%) pts in OLT. The most common TRAEs in CT were dry mouth (17%) and dysphagia (18%). These AEs were the most common in OLT. Withdrawal due to AEs occurred in 2 (<1%) pts in CT and 40 (6%) pts in OLT. One (<1%) pt withdrawal in CT and 34 (5%) in OLT were due to TRAE. The majority of AEs were mild to moderate in severity. The most common severe AEs were dry mouth (6%), dysphagia (2%), and headache (2%). Serious AEs were reported by 10 (3%) pts in CT and 122 (18%) in OLT; 1 (dysphagia) was a TRAE. No deaths were treatment-related.

Conclusions: BoNT-B doses up to 25 K U appear safe in CD. The most common TRAEs are dry mouth and dysphagia, which were typically mild to moderate in severity and infrequently lead to discontinuation.

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Keywords: Botulinum Toxin Type B; Safety; Adverse Events
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71. Botulinum toxin therapy for laryngeal dystonia and other hyperfunctional laryngeal disorders

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Botulinum toxin decreases hyperactivity with the blockade of the release of acetyl choline. We first injected a case of laryngeal dystonia in April 1984, and since this time have over 1400 patients. These include the treatment of adductor and abductor spasmodic dysphonia, adductor respiratory dystonia, and Singer's dystonia. The use of botulinum toxin for focal laryngeal dystonia (spasmodic dysphonia) has become the "gold standard" for the management of this disorder.

The toxin has also been used for many other hyperfunctional laryngeal disorders including essential voice tremor, muscle tension dysphonia, puberophonia, arytenoids rebalancing, hyperfunctional contact granulomas and nodules, tracheoesophageal speech failures, and cricopharyngeal achalasia. A review of technique, dosing, and results will be presented.

Keywords: Larynx; Botulinum toxin; Dysphonia
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72. Botulinum toxin in Hallervorden–spatz syndrome

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Hallervorden–Spatz Syndrome (HSS) is a rare autosomal-recessive pantothenate kinase-associated neurodegenerative disorder. The clinical phenotype includes dystonia and parkinsonism, among other neurological manifestations. Pharmacotherapies for dystonia, although sometimes efficacious, may have a transient effect. There are few reports regarding specific uses of Botulinum Toxin (BT) in management of these patients. We present two cases, with definitive HSS, treated with BT. (1) A 17-year old male, with neuropsychiatric symptoms beginning at 9 years. At 14 years, he developed bilateral hand dystonia that initially improved with medical treatment. It progressed to a generalised dystonia, with oromandibular, cervical, axial and lower limb involvement. Cervical, oromandibular and limb dystonia was treated with BT with a temporary good response. (2) A 28-year-old female, who presented with dystonia and parkinsonism. Dystonia became worse and started to involve craniofacial (blepharospasm and oromandibular dystonia) and limb muscles. She has been treated with BT for more than 10 years with good response. BT treatment has been enough to control dystonia with easier chewing and the disappearance of a gum lesion that had developed.

Conclusion: Although there is no specific treatment for HSS, there are disabling symptoms that may be ameliorated by BT applications, improving the quality of life for patients and their caregivers.

Keywords: Hallervorden–Spatz Syndrome; Botulinum toxin
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73. Ultrasound guided intramuscular injection of botulinum toxin A in a patient with writer's cramp—A case report

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A 56-year-old male with recalcitrant focal dystonia (writer's cramp) of the right thumb was referred to our clinic for worsening of dystonia and functional decline.