Upper Limb Assessment & Treatment Guides

2: Botulinum Toxin

## Introduction / Background / Purpose

**Post Stroke Spasticity:**

Literature suggest that 20% to 40% of people who have experienced a stroke will develop spasticity (Zorowitz, Gillard & Brainin, 2013). Spasticity can lead to pain, contractures and increased risk of pressure areas. Functionally, it can affect an individual’s mobility and activities of daily living such as dressing and managing personal hygiene. It can also impact on quality of life and requirement for carer assistance (Royal College of Physicians RCP, 2009).

**Spasticity Management using Botulinum Neurotoxin:**

There is evidence for Botulinum Neurotoxin (BNT) as an effective intervention for managing spasticity (RCP, 2009). BNT works by altering the function of the neuromuscular junction, which weakens contraction of the injected muscles. The clinical effect develops over four to seven days and alters neuromuscular function for 12-16 weeks. Clinical weakness can be detected in the injected muscle during this timeframe (Shaw et al, 2011). Botulinum Toxin is marketed by two companies in New Zealand - Botox or Dysport.

*The* ***‘Spasticity in Adults: Management using Botulinum Toxin National Guidelines’*** *were published by the Royal College of Physicians (RCP) in 2009. These are a useful resource for more in depth information on BNT for spasticity.*

The primary goals of managing post-stroke spasticity include:

* To reduce disability
* To avoid progression of impairment
* To provide relief from symptoms
* To improve quality of life of the patient as well as their caregivers.

(RCP, 2009; Barnes & Johnson, 2008).

## Competencies required

Botulinum Toxin is a registered medication and can only be administered by a medical doctor in New Zealand.

Assessment for Botulinum Toxin intervention and provision of follow-up therapy is undertaken by an Occupational Therapist or Physiotherapist.

## Equipment required

See ‘Intervention’ below.

## Procedure

**Key points for effective spasticity management using Botulinum Neurotoxin:**

* Appropriate patient selection
* Development of clear goals for intervention
* Provision of information on treatment and consent
* Muscle selection agreed between treating clinician and IDT
* Appropriate follow-up therapy
* A collaborative interdisciplinary approach.

**Patient Selection**

Patients should be selected on the basis of:

* Problem attributed to focal or multi-focal UL spasticity, rather than fixed contracture
* Provocative factors for spasticity have been excluded or treated
* Condition likely to respond to BNT injection
* No contraindications to BNT injection
* Goals of treatment have been determined, with patient input
* Arrangements in place for implementation of appropriate physical treatment strategies and monitoring
* Appropriate outcome measures identified
* Informed consent for treatment from patient, or family assents on their behalf.

(RCP, 2009)

**Assessment:**

Evaluation of the impact of interventions should include measurement at the ICF levels of Impairment, Activity and Participation (RCP, 2009). These should be completed pre- and post-intervention.

The following outcome measures can be considered:

|  |  |
| --- | --- |
| **ICF Level** | **Outcome Measure** |
| **Impairment** | Tardieu Scale  Modified Ashworth Scale  Range of motion measurements  Pain rating (Visual Analogue Scale)  Spasm frequency count  Photos of joint position |
| **Activity**  (Consider both active and passive) | **Active:**  Canadian Outcome Performance Measure (COPM)  Goal Attainment Scaling (GAS)  Arm Activity Scale (ArmA)  UL Motor Assessment Scale  Photos/videos  **Passive:**  Arm Activity Scale (ArMA)  Leeds Adult Spasticity Impact Scale (LASIS)  Carer rating of ease of care (VAS) |
| **Participation** | Stroke Specific Quality of Life Scale (SS-QoL)  Self-rated body image  Photos/videos |

**Intervention:**

* Unopened vials of Botox® and Dysport® should be stored at temperatures between 2–8°C.
* Once reconstituted, Dysport® is stable for up to eight hours in a refrigerator at 2–8°C and Botox® may be stored in a refrigerator at 2–8°C for up to 24 hours.
* The planning and siting of the injections should be undertaken by the clinician in consultation with the MDT.
* Larger superficial muscles may be identified with knowledge of surface anatomy.
* Smaller, less accessible muscles may require additional techniques to ensure correct placement of the injection, including:
  + EMG to confirm placement within the muscle
  + Nerve or muscle stimulation may be useful to confirm placement
  + Imaging, such as ultrasound
* The best sites for injection are theoretically the nerve end-plate zones deep in the muscle bulk. Small and moderate-sized muscles will usually respond to BT injected simply into the belly of the muscle.
* It is important to document the dose and dilution, the type, and the location of BT, and the

number of injection sites per muscle.

**Post-Intervention follow-up:**

The RCP Guidelines (2009) recommend BNT intervention is followed by:

* A therapy review 7-14 days post-treatment
* A review at 4-6 weeks to assess effect
* A review at 3-4 months to plan for future management

Therapy following BNT Intervention can include:

* Orthotics/splinting

Ensure there is a system to review the orthotics/splinting provision, provide new orthoses

as required and assess patient compliance

* Provide patient education on stretching regimes and guidance on participating in

activities

* Provide therapy to increase muscle strength of the opposing muscle groups
* Consider other treatments that may enhance the effects of BT such as constraint therapy

or electrical stimulation as appropriate

* Functional electrical stimulation of the *antagonist muscle* may help to build up muscle

strength and so enhance functional benefits

* active NMJs take up BT more avidly than NMJs at rest, and there is some evidence that

electrical stimulation of the *injected muscle* may enhance the anti-spastic effects of BT

(Hesse *et al* 1998). However, it is necessary to stimulate the motor point or the nerve to

the muscle, in order to activate the NMJs to achieve this effect

(RCP, 2009)

## Inclusion / Exclusion Criteria

For a full list of contraindications and special warnings and precautions for the use of BT,

clinicians should refer to the product SPC at www.emc.medicines.org.uk.

## Precautions

The maximum recommended dose in limb spasticity is 1,000U Dysport® or 360U Botox® in a

single adult injection session. Larger doses carry increasing risk of systemic adverse effects.

Serious adverse events are rare, but mild and transient adverse effects may occur.

Adverse events may include:

* *local muscle weakness* from toxin spread to nearby muscles
* *dysphagia* occurs mainly when high doses are used around the neck or proximal upper
* limb
* *respiratory failure* has not been reported in adults, although there have been isolated case
* reports in children with cerebral palsy
* *autonomic dysfunction*, if it occurs, is almost always sub-clinical
* *‘flu-like’ symptoms* for up to a week, at some point in the month after injection, but are transient and mild
* *Rash*
* *brachial neuritis* (very rare) following local injections, or
* *altered taste.*

## Evidence

There is now a substantial amount of evidence reporting the effectiveness of BNT in reducing spasticity at the level of impairment (Baker and Pereira, 2013).

Evidence for the effectiveness of Botulinum Neurotoxin for improving active functional use of the hemiplegic upper limb remains inconclusive. There is increasing literature supporting a positive effect on passive upper limb function (for example the ease of washing the hand or axilla or dressing a limb) (Shaw et al, 2011).

Although evidence is conflicting regarding the use of BNT for pain, mainly due to low quality trials (Singh & Fitzgerald (2010)

Doan et al (2012) report that for people experiencing post-stroke ULS, the level of caregiver burden is significantly related to levels of disability in the areas of hygiene and dressing. There is research to suggest that BNT can decrease this care burden (Lam et al., 2012; Bhakta et al., 2000).

The majority of studies reviewing BNT use for ULS have focussed on patients more than three months post-stroke.

## Information for Patients / Families / Whanau

See attached sheets:



**References:**

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