EVIDENCE-BASED GUIDANCE FOR PHYSIOTHERAPISTS

The use of Botulinum Toxin in Children with Neurological Conditions
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This guidance is targeted at paediatric physiotherapists involved in the management of children with neurological conditions where botulinum toxin (BTX-A) may be an appropriate adjunctive treatment.

To date there are no standardised pathways or consensus of practice for providing BTX-A injection services for children. Current provision and practice varies from one locality to another throughout the UK.

Nationally, paediatric physiotherapists have expressed a need for evidence/consensus-based guidance as there is little specific advice regarding physiotherapy intervention following BTX-A treatment.
BOTULINUM TOXIN WORKING PARTY

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ACKNOWLEDGEMENTS

The following organisations were consulted:

Association of Paediatric Chartered Physiotherapists (APCP)
Chartered Society of Physiotherapy (CSP)
Evidence Based Child Health Unit, Institute of Child Health, Royal Liverpool Children’s NHS Trust, Alder Hey
Members of The Scoping Groups: Angela Black, Dawn Walton, Pam Chimiai, Pat Clements, Sue Kelly, Susan Cleverley, Jill Davis, Jeanne Hartley, Valerie Kennedy, Sheila McNeill
UK Spasticity Forum

The Working Group would also like to thank all those paediatric physiotherapists who responded to the APCP National Botulinum Toxin Survey, via the national study day and through the iCSP website.

The working party meetings were also sponsored by educational grants from:
Association of Paediatric Chartered Physiotherapists
Allergan Ltd
Ipsen Ltd

The writing and printing of the document were also sponsored by an unrestricted educational grant from Ipsen Ltd.
EXECUTIVE SUMMARY

• Botulinum toxin (BTX-A) is an established clinical tool in the management of children with neurological disorders. Current clinical practice has seen an expansion of the clinical indications for BTX-A, with its increasing use in the treatment of pain and dystonia as well as dynamic spasticity.

• The selection of the appropriate child for injection, the target muscle(s), treatment goals, and the post-injection programme are a team decision. This should involve the child and their family, as well as the multidisciplinary team (MDT). The child’s physiotherapist plays a key role in this process.

• Physiotherapists who are experienced in the assessment and treatment of growing children with neurological conditions have the knowledge and skills required to assess the suitability for BTX-A treatment, and to select the appropriate post-injection management.

• Accurate patient assessment identifying the primary problem, and the resultant muscle groups responsible, will result in more successful treatment with BTX-A. This needs to be used in conjunction with an ongoing therapy programme with specific post-injection management. Pre- and post-injection assessments are required for appropriate patient selection, to set realistic goals and to review outcomes.

• In most cases BTX-A is unlikely to be successful when used in isolation. In order to maximise its effect, it should be used in conjunction with other appropriate management strategies such as targeted motor training, strengthening, stretching, orthoses etc. A post-injection management programme is likely to optimise the effects of BTX-A. However, to date there is no consensus regarding content, timing and frequency.

• Before considering whether or not a child may benefit from BTX-A treatment, it is important that the relevant support services are in place for the child and their parents or carer so that an appropriate post-injection management programme can be planned and carried out. If follow-up services are inadequate, the use of BTX-A may not be appropriate. The MDT also needs to consider the ability of child and family to participate and cooperate with a post-injection management programme.

• In all cases, there should be active communication between the BTX-A injection services and the local team. This should involve close liaison between the treating physiotherapist and the injecting team. The responsibility for the child’s ongoing physical management programme should remain with the referring team.

• Physiotherapists should continue to be aware of, and contribute to, research into current clinical practice with BTX-A. This will assist in extending the existing knowledge base and further refine its use. Further research is required specifically to look at the adjunctive treatments which are used in conjunction with BTX-A. It is this combination of BTX-A with adjunctive interventions that is most likely to result in a successful outcome for children with neurological impairments.
INTRODUCTION

The adverse effects of spasticity on the growing child are well documented (Graham et al 2003). Botulinum toxin (BTX-A) has been used over the last 15 years in the management of dynamic spasticity in the child with a neurological condition. There is increasing clinical evidence to support its use, but there remains a paucity of practical guidance available for paediatric physiotherapists.

Paediatric physiotherapists are key members of the multidisciplinary team (MDT) involved in the management of children with neurological conditions. They have the skill set required to assess the need for BTX-A in this population, and are therefore ideally placed to be directly involved with decision making, evaluation and ongoing management of children undergoing BTX-A (Boyd et al 1999).

This guidance is targeted at paediatric physiotherapists involved in the management of children with neurological conditions where BTX-A may be an appropriate adjunctive treatment. It is based on the available clinical evidence together with expert opinion. Current practice as outlined in the document is based on expert consensus from 16 established paediatric BTX-A services within the UK. This has been further supplemented with information provided in the APCP National Survey examining ‘The role of paediatric physiotherapists in the use of botulinum toxin A – a reflection of current practice (2006)’.

The scientific evidence has been systematically reviewed using the Scottish Intercollegiate Guidelines Network (SIGN) www.sign.ac.uk. Throughout the document the recommendations have been graded where appropriate (see Appendix 1) to provide the reader with an indication of the effectiveness of the intervention in relation to the level of scientific evidence.

This is a consensus document of good practice. It is not intended to be a rigid set of rules, but a tool to assist and inform the clinician in the areas of:

- Patient selection
- Assessment, goal setting and outcome measures
- Post-injection management
- Communication
- Audit

It is important to note that this guidance is based on current practice, which includes off-license usage of BTX-A.

Details of the practical application of BTX-A (such as injection technique and dosage) is beyond the scope of this guidance. For those physiotherapists interested in learning more about injection technique or how to become a non-medical injector, we would direct the reader to the practical techniques of BTX-A injections as covered in ‘The role of physiotherapists in the management of spasticity with botulinum toxin: a consensus guideline’, a supplement produced in association with Guidelines.
BACKGROUND

CURRENT PRACTICE

Within the UK there appears to be no agreed or standardised pathway for paediatric BTX-A injection services, and current provision varies depending on locality.

Children receive BTX-A injections usually via one of the following routes:

- Children may be injected by individual practitioners (such as a paediatrician, orthopaedic surgeon, neurologist or occasionally therapy injectors). Ideally this is carried out in co-ordination with follow-up services, but may sometimes be performed as an isolated procedure.
- Children may be referred to a local injection therapy team, who ideally would co-ordinate assessment and follow-up with the child’s individual therapist and orthotics department.
- Where there is no BTX-A service available locally, children may be referred to one of a limited number of tertiary centres which provide BTX-A/spasticity management services.

BTX-A ADMINISTRATION

In children, pain management in conjunction with the injection procedure is an important issue.

Children are usually injected under one of the following methods of sedation:

- General anaesthesia
- Oral sedation (such as Midazolam)
- Nitrous oxide (Entonox) sedation

This may be carried out in conjunction with topical analgesia such as EMLA/AMITOP/ethyl chloride spray.

Sedation varies between centres and depends usually on the number of injections, age of the child, respiratory state and resources available.

The children receive their injections using some form of accurate localisation technique, such as:

- Palpation/needle movement
- EMG guidance
- Nerve stimulator
- Ultrasound (this is increasingly becoming the technique of choice to identify muscles in paediatrics as it is precise and non-invasive (Heinan et al 2006))

Although physiotherapists are not always directly involved with the injection process, they have an important role to play in liaison with the injecting centre prior to injection. In many cases they provide advice regarding muscle selection, timing of repeat injection and in some cases are part of the decision-making process regarding the most appropriate method of sedation for the child.
BOTULINUM TOXIN

Indications

BTX-A is indicated for the treatment of focal spasticity. The evidence for its use is well documented and will not be addressed here. Please refer to the Summary of Product Characteristics (www.emc.medicines.org.uk) for the specific indications for each branded product.

Mode of action

BTX-A is a local muscle relaxant which is highly selective for peripheral nerve terminals containing acetylcholine. When injected into muscle the toxin is taken up into the nerve terminal by endocytosis. Once inside the nerve cell, BTX-A prevents the release of acetylcholine into the synaptic cleft resulting in a reduced muscle contraction. BTX-A is taken up by the neuromuscular junction within 12 hours. The onset of the response varies, but usually occurs gradually over the first week. There can be a huge variation in clinical response with effects observed immediately, or in some cases after 2-3 weeks. The effect of BTX-A is temporary; recovery of the nerve terminal takes place via ‘sprouting’ (re-establishing the original neuromuscular connection), this takes place gradually over 12-16 weeks. Although the clinical response may vary, generally the injected muscles show some detectable weakness for 3-4 months. In some cases the functional benefits of BTX-A may continue long after the chemical effects of the BTX-A have gone.

Due to the temporary effect of BTX-A, repeat injections may be required. The recommended minimum time interval for re-injection is 3 months; (more frequent re-injection is associated with a higher incidence of side effects and antibody formation).

The ideal frequency of re-injection in the paediatric population has yet to be established and depends on timely clinical assessment and evaluation. However, in view of the paucity of evidence of the effect of BTX-A on growing muscle, and the aim to prolong the effect with adjunctive measures, most paediatric centres limit their frequency of re-injection to a maximum of two injection sessions a year. Usually there is a re-injection interval of 6-12 months, unless specifically indicated for pain or acute dystonia interfering with function, which may require more frequent re-injection.

References

SECTION A: PATIENT SELECTION

Although licensed only for use in cerebral palsy, BTX-A may also be appropriate for children with:

- Post-traumatic brain injury
- Genetic conditions (i.e. hereditary spastic paraplegia)
- Metabolic conditions (i.e. mitochondrial disorders)
- Neurodegenerative disorders

A child should be considered for BTX-A treatment where there is focal, dynamic spasticity and/or dystonia which may, now or in the future, interfere with function, care-giving, result in torsional abnormalities or cause pain [D].

KEY CONSIDERATIONS

Age

There is no evidence to suggest that age is an absolute criteria for patient selection. Research supports positive results for BTX-A treatment at all ages, but generally younger children (< 8 years) are considered most appropriate (randomised controlled trials reviewed ages from 2-16 years).

Recommendations

- Younger children are considered more appropriate for BTX-A treatment as they are less likely to have established fixed soft tissue, bony torsional abnormalities, or to have learned compensatory movement patterns in the presence of long-established spasticity/dystonia [B]
- BTX-A may be appropriate for the older child who still has a dynamic component to their functional problem when used in conjunction with other treatment modalities [B]

Muscle selection

BTX-A works by reducing the dynamic component of overactive spastic or dystonic muscles. Appropriate muscle selection is a key factor. It is important to identify the specific muscles involved in causing the child’s primary functional problem.

The highest quality studies have concentrated on investigating the effects of injections into gastrocnemius and/or soleus muscles in the ambulant child with dynamic equinus (the licensed use of BTX-A), and have shown improved clinical and functional outcomes at all ages.

More extensive use of BTX-A in the treatment of other muscle groups remains ‘off-license’. Where doses and muscle groups represent appropriate but unlicensed use of BTX-A, this is however in line with agreed clinical practice.

There have been fewer studies, mainly of lower evidence levels, investigating outcomes for other lower limb muscle groups in ambulant children. Successful outcomes have been reported to correct a variety of gait problems, including crouch, scissoring, and equinovarus/varus foot deformity. The muscles injected have included tibialis posterior, peronei, hamstrings, hip adductors, and hip flexors.

There are relatively few studies involving non-ambulant children, but evidence suggests that injections into adductors may reduce the rate of hip subluxation.
Other outcomes for non-ambulant children include reduced spasm/pain, (including the perioperative period), improved caregiving, and improved sitting. The muscles injected have included hip flexors, adductors, hamstrings and quadriceps. More recently positive outcome has been reported following injections to the trunk muscles (including paraspinals and shoulder girdle) to improve posture.

Studies investigating BTX-A in the upper limb suggest improvements following injections into a number of muscles in the arm and hand. Initial work with BTX-A injections to the upper limb, demonstrated an improvement in cosmesis and little change in function. More recent work has highlighted a positive correlation with BTX-A and functional improvement.

**Number of muscle groups injected**

BTX-A, although recognised as a focal treatment for dynamic spasticity, is increasingly used for multi-level injections. These may offer both the ambulant and non-ambulant child a more comprehensive management strategy in one episode.

**Muscle selectivity**

In predicting which children may benefit from BTX-A, there is evidence within the literature to suggest a correlation with a child's ability to perform isolated movements pre-injection, and a positive outcome post-injection in recruiting both agonist and antagonist muscle activity.

The following factors do not preclude treatment with BTX-A, but proceed with caution if the patient has:

- **Fixed contractures** – most studies do not exclude the presence of fixed contractures, but BTX-A alone will not lengthen shortened muscles, and it may need to be considered in conjunction with other treatment modalities [B]
- **Established bony deformities**: BTX-A cannot alter torsional abnormalities [B]
- **Marked muscle weakness**: reducing spasticity may unmask marked muscle weakness which may have a detrimental effect on function [D]
- **Generalised spasticity**: where alternative methods of spasticity management may be more appropriate [D]
- **Problems with implementation of an effective post-injection management programme** [D]

**Recommendation**

BTX-A works by reducing overactivity in spastic or dystonic muscle. Successful outcome therefore depends on accurate selection of the muscle(s) primarily responsible for the identified problem [B].

**References**

- Ade-Hall RA, Moore AP. Botulinum toxin type A in the treatment of lower limb spasticity in cerebral palsy. The Cochrane Database of Systematic Reviews 2000 Issue 1 Art No: CD001408 DOI: 10.1002/14651858. CD001480


SECTION B: ASSESSMENT, GOAL SETTING AND OUTCOME MEASURES

ASSESSMENT

Pre-injection

- Following an initial screening for suitability for BTX-A injections the child should be assessed, ideally within the four weeks prior to injection. At this stage goals should be agreed.

Two further assessments are recommended post-injection:

- Early post-injection phase (at peak chemical effect), around 3-6 weeks. This will inform how best to target ongoing post-injection management. In the early post-injection phase, a positive change in the range of movement, dynamic spasticity, or pain would normally be expected.

- Late post-injection phase (when the chemical effect of the toxin has disappeared) between 3 and 6 months. This will inform the decision as to whether further BTX-A injections are indicated, and the required time scale, as well as reviewing long-term management such as referral on to surgical services or back to the local team [D].

Clinical note

In the initial post-injection phase there may be some deterioration in function due to changes in tone and range of motion (ROM), this usually resolves within 4-6 weeks post-injection.

There may be a difference in timing of response dependent on the level of neurological involvement. The child with diplegia or total body involvement may show earlier changes (between 2 and 4 weeks) post-injection. However, a child with hemiplegia may show later changes i.e between 4 and 6 weeks (Baker et al 1999). This may have implications for the timing of the post-injection reviews.

GOAL SETTING

The literature identifies success with the following functional goals (in many cases there may be overlap in goals with the ambulant and non-ambulant child):

Ambulant

- Functional walking may improve [C]
- Appearance of walking may improve [B]
- Gross motor skills may improve e.g. standing, transfers, sitting ability [D]
- The risk of deformity may be reduced in the short-term and may delay surgical intervention [B]
- Improved tolerance of orthoses or casting [D]
- Reduction in painful spasms [D]
- Improved sleep pattern [D]

Non-ambulant

- Personal care and hygiene may improve [D]
- Nursing care may be easier [D]
- Reduction in pain (including peri-operative use) [D]
- Improved sleep pattern [D]
- Improved tolerance of postural management equipment [D]
- Improved quality of life [D]
Upper limb
- Personal care and hygiene may improve [D]
- Cosmesis may improve [D]
- Function may improve [C]

Goal setting, measurement and assessment should be a collaborative process, involving the child and their parents or carer, as part of a MDT [D].

Good practice states that specific goals should be set with the relevant outcome measure. All parties should understand and agree to the goals which should adhere to the SMART directive (see Table 1).

**Table 1: SMART directive**
Goals must be SMART
- **S** = Specific
- **M** = Measurable
- **A** = Achievable
- **R** = Realistic
- **T** = Timed

Above all the goals should express realistic, achievable benefits that are meaningful to the child and their parents or carer.

**OUTCOME MEASURES**

**Measurement selection**
Measurement selection should follow the guidance outlined in The Chartered Society of Physiotherapy (CSP) Core Standard (see Table 2).

**Table 2: The Chartered Society of Physiotherapy Core Standard 6**
Taking account of the patient's problems, a published, standardised, valid, reliable and responsive measure is used to evaluate the change in the patient’s health status:
- The physiotherapist selects an outcome measure that is relevant to the patient’s problems
- The physiotherapist ensures that the outcome measure is acceptable to the patient
- The physiotherapist selects an outcome measure that he/she has the necessary skill and experience to use, administer and interpret
- The physiotherapist takes account of the patient’s welfare during the administration of the measure
- Written instructions in the manufacturers manual, test designer’s manual or service guidelines are followed during the administration and scoring of the measure
- The result of the measurement is recorded promptly
- The same measure is used at the end of the episode of care
**Type of measurement**

There are a variety of appropriate outcome measures available (see Table 3). Ideally measures used should include the domains of both systems and activity/participation measures.

The selection of the outcome measure depends on the treatment goal(s) selected. The tool selected should be sensitive enough to detect the change that the therapist is hoping to bring about with BTX-A.

Table 3 lists the outcome measures according to the level of disability they are most commonly used to assess. The level of evidence reported is for studies involving BTX-A rather than an indication of the reliability of the measures. For more information regarding outcome measures refer to APCP/PPIMS pack on Paediatric Outcome Measurement (2005).

**Table 3: Outcome measures**

(The outcome measures have been divided into ambulant and non ambulant categories for ease of reference; in reality they may overlap)

### AMBULANT CHILD

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<th>SYSTEM MEASURE</th>
<th>ACTIVITY MEASURE</th>
<th>PARTICIPATION MEASURE</th>
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<tr>
<td>ROM [B]</td>
<td>GMFM [D]</td>
<td>COPM [D]</td>
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<tr>
<td>Gait analysis:</td>
<td>Gait analysis: [C] Temporal spatial features i.e speed, cadence, step length</td>
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<td>- 3D gait analysis [B]</td>
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<td>- Video gait analysis [C]</td>
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<td>- Physicin rating scale</td>
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<td>- Edinburgh gait scale</td>
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<tr>
<td>Muscle Power MRC [D]</td>
<td>Timed walk [D]</td>
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<tr>
<td>Selective Muscle Control (SMC) [D]</td>
<td>Timed up and go*</td>
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<td>Gillette FAQ [D]</td>
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### NON-AMBULANT CHILD

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<tr>
<td>ROM [B]</td>
<td>PEDI [D]</td>
<td>Quality of life</td>
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<tr>
<td>Pain Scales: Paediatric Pain Profile [B] The Faces Pain Scale-Revised</td>
<td>Chailey levels of ability*</td>
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<td>Tone measures:</td>
<td>GAS [D]</td>
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<td>- Ashworth scale [D]</td>
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AHA = Assisting Hand Assessment; BFMF = Bimanual Fine Motor Function; COPM = Canadian Occupational Performance Measure; Gillette FAQ = Gillette Functional Assessment Questionnaire; GAS = Goal Attainment Score; GMFM = Gross Motor Function Measure; MACS = Manual Ability Classification System; PEDI = Pediatric Evaluation of Disability Inventory; QoL = Quality of Life; QUEST = Quality of Upper Extremity Skills Test; ROM = Range Of Motion; SHUEE = Shriners Hospital Upper Extremity Evaluation; WeeFIM = Paediatric Functional Independence Measure

*Measures that are used in clinical practice but to date have not been reported in the literature to specifically assess the use of BTX-A.
Some measures may not be sensitive enough to detect short-term change as a result of BTX-A injections. For example, the activities of the daily living section of the PEDI [D] and some dimensions of the GMFM [B], but they may be able to show change in the longer term (Slawek et al 2003). Therefore, in some children it may be more appropriate to measure changes in tone and range of movement within the first 3-6 weeks, but to wait until 3-6 months post-treatment to measure functional changes.

**Recommendations**

- All children should have a minimum assessment consisting of systems measures such as ROM and tone and where appropriate pain scales [D]
- Ideally all patients should have some measure of activity and participation to record functional goals [D]
- An additional minimum requirement for all ambulant patients undergoing BTX-A should be a recorded observational gait analysis [D]

**References**


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**TABLE**

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<td>SYSTEM MEASURE</td>
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*Measures that are used in clinical practice but to date have not been reported in the literature to specifically assess the use of BTX-A.
SECTION C: POST-INJECTION MANAGEMENT PROGRAMME

BTX-A AS AN ADJUNCTIVE TREATMENT

BTX-A should be used in conjunction with, and as part of, a long-term management programme. Specific goals for its use should be agreed with the child, their parents or carer and the MDT.

Depending on the agreed goals, treatment with BTX-A, when used with other interventions, can provide a ‘window of opportunity’ to achieve longer-term benefits for the child with a neurological condition. It is therefore imperative that a timely and appropriate physiotherapy management programme is in place during the post-injection period.

Without therapy support, the benefits of the intervention are unlikely to be maximised. The child’s physiotherapist is best placed to take responsibility for developing and co-ordinating an appropriate post-injection management programme, with advice and support from tertiary/injecting teams when required or appropriate.

The selection and timing of any follow-up intervention will depend on:

- The agreed goals for the BTX-A injections
- The ability of the child and their parents or carer to participate
- The availability and structure of local resources

INTERVENTIONS

Recommendation

BTX-A is less likely to be successful when used in isolation from other management strategies. The guidance recommends that appropriate, timely interventions, used in conjunction with BTX-A, can improve the outcome for many children with neurological conditions [D].

The following specific interventions have been reported both in the literature and in the APCP National Survey to potentiate the effect of BTX-A, but to date there is no consensus regarding timing and frequency.

Physiotherapy

Although physiotherapy is recommended in conjunction with BTX-A, as in the case of much therapeutic intervention with neurological conditions, there is little evidence in the literature to support its specific effectiveness. To meet the therapeutic goals post-injection, a combination of impairment level interventions and functional activity based interventions have been reported in the literature.

Strategies described post-intervention include:

- Neurodevelopmental therapy
- Targeted motor training
- Gait/locomotion training
- Activities of daily life / functional training
- Therapeutic horse riding
- Constraint induced movement therapy
- Motor re-learning programme
- Home activity programmes
- Muscle strengthening

These were consistent with the therapeutic interventions highlighted in the APCP National Survey.
Timing and frequency
The clinical response to BTX-A varies between children. It is therefore impossible to be prescriptive about the timing of intervention post-injection. It is the responsibility of the child’s physiotherapist to assess outcome post-injection and identify the treatment required to potentiate the effect of BTX-A, including the timing and frequency of this intervention.

In the APCP National Survey, 69% of respondents would increase therapy provision in the acute post-injection period when clinically indicated. The favoured approach being increased blocks of intensive therapy usually for 6 weeks within the acute phase.

Recommendation
The child’s therapy programme should be reviewed in the initial post-injection period in order to implement any changes required due to an alteration in tone, range of motion or function [D].

Muscle stretching
Sustained stretch is widely used to prevent contracture development. There are few studies which examine the success of stretching programmes, and no specific studies relating to BTX-A. However, improvement in a stretching programme is a frequently quoted goal in relation to BTX-A. In the APCP National Survey, 73% of respondents worked specifically on muscle stretching post-injection.

BTX-A by reducing a child’s dynamic tone, may make stretching of the injected muscles easier to perform and improve the tolerance of stretching programmes.

References
Lannin N, Clark K, Scheinberg A. New South Wales therapy practices for children with cerebral palsy who have received botulinum toxin-A. Aus Occupational Ther J 2004;51:208-212
Tardieu C, Lejapert A, Tarbary C et al. For how long must the soleus muscle be stretched each day to prevent contractures. Dev Med Child Neurol 1986;28:1-10
Muscle strengthening

Weakness is a recognised characteristic in the child with a neurological condition. In children with spastic cerebral palsy, short-term strength training programmes demonstrate functional improvements, particularly evident in gait function, without increases in spasticity or abnormal movement patterns [B].

Following BTX-A, the period of chemical denervation of the injected muscles provides an opportunity for strengthening antagonist, and where indicated, agonist muscles in motor training programmes [D].

In the APCP National Survey, 82% of respondents worked specifically on muscle strengthening post-injection.

References


Orthoses

Orthoses are commonly used for children with neurological conditions to prevent deformity, support normal joint alignment and to facilitate function. Although the use of orthotics is advocated in conjunction with BTX-A, there are few studies in the literature that examine the specific role of BTX-A and orthoses.

In the APCP National Survey, 65% of respondents stated that improved splint tolerance was a goal of BTX-A treatment and 75% would modify orthoses post-injection.

Recommendations

• Where there are problems with splint tolerance due to dynamic overactivity of the muscle, it may be appropriate to reduce spasticity with BTX-A to improve the tolerance of the orthosis [D]

• Following treatment with BTX-A, a review of the child’s orthotic prescription may be necessary, together with a review of sitting and standing equipment [D]

There are claims in the literature that night splinting and day orthoses offer sustained stretch of spastic muscle, preserve muscle length, and influence the long-term effects of BTX-A treatment. A combined approach of multi-level injections and orthoses in an integrated approach has been shown to have a longer lasting effect in comparison to BTX-A in isolation (Heinan et al 2006; Molenaars et al 1999).

However, there have been smaller conflicting studies looking specifically at the long-term carry over following night time splinting and BTX-A which have not shown any clinical significance (Rosenbloom et al 2003; Givon et al 2003).

In the non-ambulant child there has been increasing use of use of BTX-A injections to adductors and hamstrings, together with a variable hip abduction orthosis in an attempt to control hip subluxation. To date the short-term evidence has been encouraging, but the long-term radiological outcome for this combined approach remains unknown (Boyd et al 2001).
References


Green LJ, Bendel E, Schindler A et al. Are night splints a useful adjuvant for botulinum toxin therapy? AACPDM C5;11.


Casting

Immobilisation of a muscle in the lengthened position, as in casting, increases the overall musculotendinous unit length, resulting in an increase range of movement (Mcnee et al 2007).

Individually, casting and BTX-A have both been shown to be effective in increasing range of movement. Combined treatment (BTX-A + casting) is most commonly used where there is dynamic spasticity with early myostatic contracture. Comparative studies have shown a prolonged effect of improved ROM in comparison to both casting and BTX-A alone.

The time required to achieve an improved ROM has been shown to be reduced when using the combination of BTX-A and casting, versus casting alone.

There have been smaller conflicting studies which have suggested BTX-A combined with casting has resulted in an increased speed of contracture recurrence in comparison to BTX-A alone (D). However, a recent systematic review of the literature has found that the evidence both for and against casting remains weak (B).

There is great variety in casting techniques and a paucity of detail reported in the literature specifically relating to BTX-A.

Timing of casting with BTX-A

Although there is agreement in the literature regarding the indications for casting, there is no consensus regarding the timing of casting post BTX-A injection. The procedure mainly relies on local practice and service resources.

The alternatives reported in the literature are:

• Immediately post-injection or
• Delayed into the acute post-injection phase (this may in some centres coincide with the first post-injection review)

From the APCP National Survey it would appear that when casting is indicated, 73% of respondents would delay casting post-injection.

The advantages for delaying casting:

• Ability to assess the true dynamic component of the spasticity/dystonia
• Evidence from the animal models suggests that increased activity results in increased uptake of BTX-A and therefore would argue against early immobilisation
• There have been concerns expressed regarding prolonged immobilisation in the acute post-injection phase, resulting in a lack of opportunity for rehabilitation and strengthening programmes
• Comparative studies have suggested that delaying the cast application post-injection results in a more prolonged effect of increased ROM, together with less discomfort reported during the casting process.

The advantages of casting immediately post-injection:

• Ease of application, particularly if the child is sedated
• In the case of repeat injections, when a child is known to have a degree of fixed contracture and has previously responded well to a combination of BTX-A and casting.
Recommendations

• A combination of BTX-A with casting may be indicated in the presence of dynamic spasticity and mild contracture [D]
• Frequent cast changes should result in an improvement in ROM without excessive weakness post BTX-A [D]
• A combination of casting + BTX-A should result in a reduced time to achieve improvement in ROM in comparison to casting alone [D]

References


Functional Electrical Stimulation

Functional electrical stimulation (FES) has been used as an adjunct to physiotherapy to promote motor control and performance. In combination with BTX-A, it has been proposed that FES optimises the effect of reduced activity in the injected muscle. However, there is little evidence to date to support that adjuvant electrical therapy has a significant effect on outcomes measured or any increased long-term benefit. In the APCP National Survey only 5% of respondents reported using FES post-injection.

References


Positioning

Twenty four-hour postural care is widely used as a management strategy in the care of children with neurological conditions. There are to date no specific studies looking at postural management and BTX-A. However, improving postural management is a frequently quoted goal in conjunction with BTX-A. In the APCP National Survey 59% of respondents would review postural management post-injection.
COMMUNICATION

Evidence from the APCP National Survey cites lack of communication as the largest area of frustration for therapists. Without effective communication between injecting centres and local teams, a successful outcome with BTX-A is unlikely, due to lack of timely co-ordination of therapy, orthoses and equipment.

**Recommendation**

Ongoing and effective communication between all team members is crucial to a successful outcome [D].

The physiotherapist, as a key member of the team will therefore need to:

- Liaise and communicate with the other team members throughout the assessment and review process
- Discuss and agree on the goals of BTX-A injection
- Agree on the most appropriate post-injection management programme to achieve those goals
- Advise and support the child, family and all those involved in the child’s care to deliver the management programme [D]

AUDIT

It is best practice to record all stages of the BTX-A management programme.

**Audit of the use of BTX-A should include:**

- Criteria for its use
- Treatment goals
- Baseline assessment measures
- Outcome measures
- Adverse events
- Interpretation of results; follow-up treatment plan
- User satisfaction questionnaire
- Plans for future management

It is only through audit, and its relationship to best practice in the field of BTX-A, that future management can improve for children with neurological conditions.
APPENDIX I

This guidance uses the Scottish Intercollegiate Guidelines Network (SIGN) grading system to assess the evidence base:

**Table 1: SIGN grading system**

### Levels of evidence

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case-control or cohort studies</td>
</tr>
<tr>
<td></td>
<td>High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>2+</td>
<td>Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

### Grades of recommendation

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>At least one meta analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or</td>
</tr>
<tr>
<td></td>
<td>A systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or</td>
</tr>
<tr>
<td></td>
<td>Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or</td>
</tr>
<tr>
<td></td>
<td>Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or</td>
</tr>
<tr>
<td></td>
<td>Extrapolated evidence from studies rated as 2+</td>
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