VPRS Victorian Paediatric Rehabilitation Service

Information for Families

Botulinum Toxin Injections

What is Botulinum Toxin?

There are several types of Botulinum Toxin (types A, B, C, D, E, F, and G). Each has different properties and actions. This sheet will provide information about Botulinum Toxin Type A (BoNT-A), a drug which can be injected into muscles to reduce muscle spasticity, pain and spasm and improve function. BoNT-A has also been show to be effective in treating muscle dystonia. BoNT-A can also be used to help manage drooling or excessive sweating when injected into salivary and sweat glands. The trade names for the BoNT-A preparations used in Australia are Botox® and Dysport®

BoNT-A has been used in Australia to manage spasticity in children since 1994. BoNT-A is now accepted practice in the management of spasticity and dystonia in children and there is extensive published literature describing the use, dosage and positive outcomes associated with BoNT-A treatment.

How does BoNT-A work?

BoNT-A can be used to treat spasticity and dystonia in children. Spasticity and dystonia are caused by an over-activity of messages being sent from the nervous system to muscles. When injected, BoNT-A attaches to nerve endings in muscle and temporarily stops messages being sent to the muscles. This allows the muscle to relax,

and also causes some temporary muscle weakness. In combination with therapy the temporary muscle relaxation may allow for improvements in muscle length, control of movement and function.

How is BoNT-A administered?

BoNT-A is injected directly into the target muscles using a very fine needle as this may involve several injections, the procedure is usually performed whilst the child is receiving sedation. Thus, the procedure is done either in the operating theatre with General Anaesthetic or within the outpatient clinic with Nitrous Oxide ("happy gas"). Your team will decide which method of sedation is best suited to your child

Electrical stimulation and/or ultrasound imaging is used to ensure precise targeting of the muscles being injected. With electrical stimulation a small electrical current is sent through the needle at the time of injection to cause movement of the specific muscle. Ultrasound imaging is used to produce real-time pictures of the inside of the body using high-frequency sound waves to identify the correct muscle for injection. Both of these methods are safe and effective. BoNT-A, like any injection, can cause mild and temporary discomfort or bruising at the injection site. Rarely, other side effects may occur (see below). If you have any questions, please speak with the rehabilitation team.

How long does the effect of BoNT-A last?

The effectiveness of BoNT-A depends on the child's age, the severity of muscle spasticity, the degree of muscle tightness and also the therapy program. The effect of BoNT-A is not immediate, but is usually apparent around 2 weeks after the injections. The effect lasts approximately 4-6 months. The physical improvements gained during this period may be maintained in some children even after the BoNT-A has worn off.

Who decides if BoNT-A is right for your Child?

The decision to use BoNT-A as part of your child's overall treatment program will be made in consultation with you, your rehabilitation team and your community therapy team. It is important to involve your local community therapy team in the decision making process and treatment required after the procedure, and they are welcome to come to clinic appointments with your child. Once you have received an appointment for the assessment or injection clinic, please make sure your community therapy team is aware of the appointment time.

On the day of the BoNT-A injection clinic, the rehabilitation team will make a final decision with you about which of your child's muscles should be injected.

How can the effect of BoNT-A be maximised?

After the injection has occurred it is important for your child to undertake some therapy. This may be provided by the Victorian Paediatric Rehabilitation Service (VPRS) or by your local therapists. If your local therapists are going to be undertaking the ongoing therapy it is important the VPRS team discusses your child's goals and anticipated treatment with them prior to the injection date. Your child's therapy may include exercise prescription, splinting, orthotics, serial casting, strengthening and gait retraining.

Exercise Program

Following BoNT-A injections we may recommended your child receives physiotherapy and/or occupational therapy so that specific exercises can be developed aimed at stretching and strengthening muscles, and improving quality of movement. Your therapist may then develop a range of appropriate activities for your child to practice at home and at school to make the most of the BoNT-A injections.

Splinting and Orthotics

If your child usually wears a leg orthotic, night splint or resting hand splint, it must fit well at the time of injections so that their arm or leg is in the best position for stretching and/or moving. Please discuss your child's splints with your local therapists or rehabilitation team before BoNT-A injections if you have any concerns about how they fit.

Serial Casting

Some children may require casting of their arm or leg after the injections. This can be done immediately after the injections while the child is still under sedation or within the next few weeks in the outpatient clinic. The aim of serial casting is to improve muscle length in muscles that have become short ("muscle contracture"). If casting is recommended, the rehabilitation team and/or community therapy team will discuss this process with you and arrange follow up therapy. Please see separate fact sheet on Serial Casting for further information.

Review following BoNT-A injections

Your child will need to attend a clinic appointment between 2-5 weeks post BoNT-A injection so that the team can assess the effect of the BoNT-A and make plans regarding future reviews and/or treatment.

What are the side effects of BoNT-A?

BoNT-A, like any injection, can cause mild and temporary discomfort or bruising at the injection site. Rarely, other side effects may occur and these are listed below.

A short flu-like illness with general tiredness and fever can be experienced in the first few days after treatment. This may occur in approximately 1% of patients.

There may be muscle weakness greater than expected in the muscles that have been injected which can temporarily affect your child's movement. Some children may appear clumsier and fall more often for 1-2 weeks after treatment.

Some children's bladder control may be affected for a short time after the injections causing unexpected wetting in the first 2-3 weeks post-injection.

Very rarely, mild generalised muscle weakness can occur due to the whole body taking up a small amount of BoNT-A. This does not usually result in any serious problems. However, in children who already have significant swallowing difficulties, a small change in their swallowing ability from the increased weakness may increase the risk of aspiration (breathing food or fluid into their lungs).

If you notice your child has increased difficulty with swallowing or coughing after BoNT-A, you should immediately contact your rehabilitation doctor and come into the hospital to have this assessed more fully.

Skin rashes, itchiness and allergic reactions at the injection site may occur on rare occasions.

BoNT-A may also used to manage drooling by injection into salivary glands. A few years ago, media attention was directed towards complications of salivary gland injections that had occurred in several children in New Zealand. These children developed swallowing difficulties after receiving large doses and volumes of BoNT-A into their salivary glands. This resulted in significant local spread of the toxin into the adjacent swallowing muscles. The children required nasogastric tube feeds for a period of time, but then made a full recovery. The complication was felt to be directly related to both the large doses and the large dilution used.

BoNT-A contains a very small amount of human serum albumin (HSA) to stabilise the protein. After repeated doses, some individuals have developed antibody resistance to the protein in the BoNT-A preparation. This is uncommon, however when this occurs the child will respond less well to the drug.

BoNT-A is a drug with specific dosage considerations. It is important to be aware of this if your child sees more than one doctor for BoNT-A, for example for their leg or arm injections or to help with drooling. Some children may also receive BoNT-A at different hospitals. In this situation you should inform your doctor that your child has received BoNT-A treatment previously.

Both the USA Federal Drug Authority and the American Academy of Cerebral Palsy and Developmental Medicine have released statements following media attention surrounding the deaths of 4 children potentially related to BoNT-A treatment in the USA. They recommended no changes to current management or use of BoNT-A clinical practice. No deaths of children related to BoNT-A in Australia have been reported, however we continue to carefully monitor any side effects which may be related to this treatment.

Evidence reviewing the use of BoNT-A

There are several papers which the rehabilitation team can provide to you reviewing side effects in children who have used BoNT-A,

1. Kolaski K, Ajaizan SJ, Passmore L, Pasutharnchat N, Komas LA, Smith BP. 'Safety profile of multilevel chemical denervation procedures using phenol or botulinum toxin or both in a paediatric population' *Am J Phys Med Rehabil* 2008 Jul; 87 (7): 556-66.

2. Simpson DM, Gracies J-M, Graham HK, *et al.* 'Assessment: Botulinum neurotoxin for the treatment of spasticity (an evidence-based review).' *American Academy of Neurology* 2008; 70 p 1691- 1698

3. Bakheit AM, Severa S, Cosgrove A, *et al*. Safety profile and efficacy of botulinum toxin (dysport) in children with muscle spasticity. *Dev Med Child Neurol* 2001;43:234-8.

4. Naumann M, Jankovic J. Safety of botulinum toxin: a systemic review and meta-analysis. *Curr Med Res Opin* 2004;20:981-90.

5. Howell K, Selber P, Graham HK, Reddihough D. 'Botulinum neurotoxin A: An unusual systemic effect' *Journal of Paediatrics and Child Health* 2007; 43 p 499-501

6. Mohamed KA, Moore AP, Rosenbaum L. Adverse events following repeated injections with botulinum toxin in children with spasticity. *Dev Med Child Neuro* 2001;43:791-92.

This information sheet is for education purposes only. Please consult with your doctor or other health professional to make sure this information is right for your child.

Contact Us

Please contact your team at Victorian Paediatric Rehabilitation Service if you have any questions or a concern regarding your child's BoNT-A injections.