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Effectiveness and indications for Botulinum Toxin Type A Treatment in children and adolescents with Cerebral Palsy - A systematic review

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ABSTRACT

Introduction: Botulinum Toxin Type A (BoNT-A) has been the standard treatment for spasticity in children with Cerebral Palsy (CP) for over 30 years. *Aim*: This review provides an overview of the effectiveness and medical indications for BoNT-A treatment in underage patients with Cerebral Palsy. *Methods*: We searched the literature on electronic databases (January 1997- January 2026), including PubMed and Google Scholar, using the following keywords: Cerebral Palsy (CP); Botulinum Toxin Type A (BoNT-A); spasticity; GMFCS scale; Multi-level treatment; and motor development. Randomized controlled trials (RCTs), meta-analyses, and systematic reviews were included. *Results*: BoNT-A injections are considered a safe and well-tolerated treatment when a minimum interval of three months is maintained between treatment sessions. Successful treatment must be individualized and integrated with intensive physiotherapy and orthotic management. *Conclusions*: It has been proven that BoNT-A is an effective and safe treatment for muscular spasticity in children with cerebral palsy. It improves grasping function and gait patterns and provides significant pain relief in cases of hip spasms. Treatment goals are dependent on the patients' GMFCS level, ranging from gait improvement (GMFCS I-III) to pain reduction (GMFCS IV-V), greatly enhancing patients' quality of life.

Keywords: Cerebral Palsy (CP), Botulinum Toxin Type A (BoNT-A), spasticity, multimodal rehabilitation, GMFCS scale, multi-level treatment, motor development.

1. INTRODUCTION

Botulinum toxin type A is increasingly used in modern medicine. Although Botox is commonly associated with aesthetic medicine, used strictly for adults to improve their appearance, it can also be helpful in other fields of medicine, even for children and adolescents. An example of such treatment is the use of botulinum toxin type A as an adjunct therapy in children with cerebral palsy. Cerebral palsy (CP) is defined as a group of permanent disorders of the development of movement and posture, causing activity limitations, that are attributed to non-progressive disturbances occurring in the developing fetal or infant brain (YaJie and BaoQin 2008; Multani et

al., 2019). It is the most common cause of spasticity in children, which will be the focus of this review. Spasticity occurs in approximately 70–80% of affected children (Hong et al., 2017). It is usually associated with periventricular white matter lesions, ischemic damage, or developmental brain abnormalities. Although the brain injury itself is static, the resulting musculoskeletal problems are progressive in nature (Strobl et al., 2015; Multani et al., 2019).

The most important challenge in the treatment of CP is managing muscle overactivity, which interferes with motor development and can lead to painful spasms and secondary structural changes in joints. This, in turn, results in numerous complications - including psychological difficulties in children and adolescents, who may feel excluded from their peers due to reduced functional ability. In this context, botulinum toxin type A (BoNT-A) became standard of care in CP over 30 years ago (specifically in 1993) (Multani et al., 2019). We should emphasize that the use of BoNT-A in children with CP is not a standalone therapy but rather an important component of a multimodal rehabilitation approach (Strobl et al., 2015; Multani et al., 2019).

2. REVIEW METHODS

Our literature search was conducted in January 2026. We searched PubMed and Google Scholar. Our review included randomized controlled trials (RCTs), meta-analyses, and systematic reviews. We focused on studies involving pediatric patients with cerebral palsy. We chose publications in English, published from January 1997 to January 2026. The exclusion criteria were these four reasons: (1) case reports and editorials; (2) studies not available as full text; (3) publications in languages other than English; (4) studies on adult populations only. Ultimately, we included 22 studies in qualitative synthesis. The article screening process followed the PRISMA guidelines, as illustrated in Figure 1.

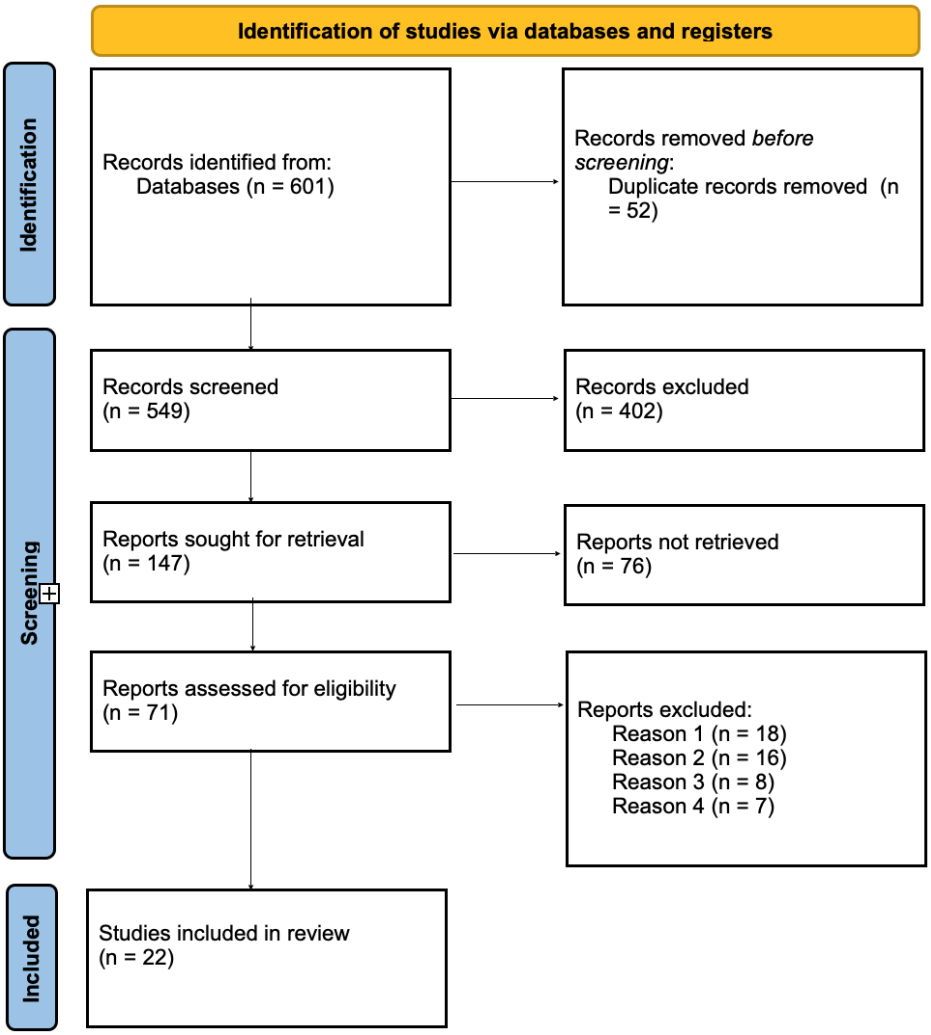

Figure 1. PRISMA flow diagram.

3. RESULTS AND DISCUSSION

Mechanism of action of Botulinum Toxin (BoNT-A)

Botulinum toxin is a neurotoxin produced by the anaerobic bacterium called Clostridium botulinum. The bacterium causes selective and reversible chemical denervation of muscles (Bjornson et al., 2007). It is considered the most potent neurotoxin known. (Multani et al., 2019) There are seven different immune types of the toxin: A, B, C, D, E, F, and G. Toxin types A and B are used to decrease muscular spasticity, but we are focusing on type A in this paper (Meholjić-Fetahović, 2007).

At the molecular level, the BoNT-A molecule consists of a heavy chain and a light chain. The light chain is a metalloprotease that cleaves a SNAP-25 protein. More specifically, chemical denervation occurs through the inhibition of acetylcholine release at the presynaptic cleft of the neuromuscular junction via the cleavage of SNAP-25. This protein is essential for synaptic vesicles containing neurotransmitters to fuse with the presynaptic membrane. As a result, muscle contraction gets weak, and muscle tone becomes reduced. That causes decreased spasticity (Lundy et al., 2009). The clinical effect of the injection usually appears within the first 12 hours after administration, although in some cases it may take up to 7 days. The peak effect is usually reached around 3 weeks after injection (Forssberg and Tedroff, 1997). This process is reversible. The neuromuscular function generally returns within 3 to 6 months. In some cases, the effect may last up to a year. The recovery of neuromuscular function first occurs through so-called "nerve sprouting", which is the formation of new nerve endings, and ultimately through the restoration of the original nerve terminals' ability to release acetylcholine and renew normal neurotransmission (Langdon et al., 2010; Hareb et al., 2020).

Indications for the use of BoNT-A and patient selection

The main indication for the use of botulinum toxin type A (BoNT-A) in children with cerebral palsy (CP) is the treatment of focal and segmental muscle overactivity, which interferes with motor function and daily activities, causes chronic pain, and may lead to the development of deformities (Langdon et al., 2010; Lundy et al., 2009). There are also several additional indications; however, they are not the focus of this paper. These include: focal dystonias (e.g., cervical dystonia, blepharospasm, writers' cramp), strabismus, chronic migraine, hyperhidrosis, sialorrhea, and overactive bladder.

A key element of patient qualification is the precise distinction between dynamic spasticity, which responds well to botulinum toxin, and fixed structural contractures (fibrosis), in which case injection will not improve the range of motion. In such cases, the patient may require surgical intervention (Camargo et al., 2009; Placzek et al., 2010). Treatment goals depend on the patients' functional level according to the Gross Motor Function Classification System (GMFCS), sex, and age (Franzén et al., 2017).

The Gross Motor Function Classification System (GMFCS) is a 5-level scale used to classify the mobility and gross motor function of children with cerebral palsy based on independent movement, use of assistive devices, or the need for a wheelchair (Table 1). Lower levels (I–III) indicate greater independence and with these children the main goals in the treatment are to improve gait pattern, increase walking speed, and prevent secondary deformities, while higher levels (IV–V) reflect severe limitations in movement and the need for significant support and with those children therapy focuses on improving comfort, reducing pain, facilitating proper positioning in a wheelchair, and supporting hygiene and daily care (the so-called care and comfort approach) (Langdon et al., 2010; Boudokhane et al., 2025).

Table 1. The Gross Motor Function Classification System (GMFCS).

Level I	Walks without limitations; runs and jumps, but speed/balance are limited.
Level II	Walks with limitations, may struggle with uneven surfaces or long distances.
Level III	Walks using a hand-held mobility device (e.g., walker, crutches).
Level IV	Self-mobility with limitations; may use powered mobility or require assistance.
Level V	Transported in a manual wheelchair; severely limited in voluntary movement.

Modern strategies, including the Key muscle and Multi-level concepts

The approach to the treatment of muscle spasticity in children with cerebral palsy has changed compared to the past. There has been a shift from single, isolated injections to a multi-level treatment strategy. This Multi-level treatment involves injecting botulinum toxin into several muscle groups at the same time, such as hip adductors, knee flexors, and the gastrocnemius, instead of focusing on a single muscle. This approach allows for a general improvement in posture and function, rather than producing only localized effects (Multani et al., 2019; Placzek et al., 2010; Schasfoort et al., 2018).

An important model is the Key Muscle Concept, in which we select specific muscles because they represent the first barrier to achieving the next stage of motor development, the so-called motor milestone (e.g., independent sitting, crawling, or standing) (Strobl et al., 2015; Placzek et al., 2010). Early initiation of therapy is recommended (often between 2 and 6 years of age), when brain plasticity is greatest and abnormal movement patterns and structural deformities are not yet fixed. This period is particularly favorable for learning new motor patterns. Dosage depends strictly on the preparation used. Botox (onaBoNT-A) is typically administered at 12–15 U/kg (maximum 300 U), Dysport (aboBoNT-A) at 20–30 U/kg (maximum 1000 U) per session (Strobl et al., 2015; Hareb et al., 2020; Placzek et al., 2010).

It is important to remember the integrated approach in the treatment of cerebral palsy. This includes combining botulinum toxin therapy with physiotherapy since intensive exercises, stretching, and strengthening after injection are essential to maintain and improve the therapeutic effect (Strobl et al., 2015). Orthoses, braces, and serial casting are also often used. The application of orthoses or casts after injection (often 2-3 weeks later, at the peak effect of the toxin) helps to lengthen muscles and widen the range of motion.

Clinical effectiveness in the lower and upper limbs and pain management

The clinical effectiveness of botulinum toxin type A (BoNT-A) in treating spasticity in children with cerebral palsy (CP) is primarily reflected in reduced muscle tone and improved motor function (Friedman and Goldman, 2011). This effectiveness has been confirmed by numerous studies that demonstrate decreased muscle tone measured using the Ashworth Scale (MAS) and the Tardieu Scale (MTS) (Terebessy et al., 2019; Mirska et al., 2019). Long-term use of botulinum toxin type A (BoNT-A) enables effective reduction of spasticity. Each subsequent injection results in an immediate decrease in muscle tone. However, improvements in range of motion (ROM) are short-lived and occur mainly after the initial treatments. Findings indicate that BoNT-A does not prevent the development of contractures. That suggests that their formation depends not only on spasticity but also on molecular processes such as collagen deposition (Tedroff et al., 2009). One of the most important long-term benefits of regular BoNT-A use is the delay or reduction in the need for invasive surgical procedures (Friedman and Goldman, 2011).

The most common injection place is the gastrocnemius muscle. We use it to treat dynamic equinus foot deformity. We also use injections into the hamstring muscles to improve knee extension during the stance phase. However, the law of diminishing returns should be considered; the toxin's effectiveness might decrease in older children or after multiple treatment cycles (Lundy et al., 2009). Studies show significant improvements in the ankle joints' range of motion, along with longer steps and faster walking speeds, particularly in children with spastic diplegia (Bjornson et al., 2007; Camargo et al., 2009). Adding injections to standard physiotherapy results in better outcomes in terms of gait improvement. However, BoNT-A does not show superiority over serial casting alone (Friedman and Goldman, 2011).

When it comes to the upper limbs, repeated injections into the wrist flexors, pronator teres, and adductor pollicis - particularly the first and second injection - result in significant improvement in limb appearance, grasping function, and self-care abilities (Multani et al., 2019; Park and Rha, 2006; Lowe et al., 2007). Studies have shown that repeated injections in the upper limb are safe and effective, especially when combined with intensive occupational and bimanual therapy (Lundy et al., 2009). This approach has a positive impact on quality of life (QOL), as confirmed by PODCI and CCQ questionnaires (Assis et al., 2008).

BoNT-A demonstrates a strong analgesic effect, particularly in children with GMFCS level V who experience painful hip spasms because of the hip subluxation. Pain reduction directly improves sleep quality and makes the caregiving activities easier (Langdon et al., 2010; Lundy et al., 2009).

Safety and long-term risks

Repeated administration of BoNT-A (including doses up to 15 U/kg) is considered safe and well-tolerated. In 89.3% of cases, no adverse implications have been reported. Studies have also shown no direct association between injections and the occurrence of serious adverse events, and the therapeutic effects stay beyond the active duration of the drug. Mild side effects, such as respiratory tract infections, fever (8.3%), muscle weakness (4.5%), or pain at the injection site, occur rarely and are usually transient. However, the risk of complications increases with doses that exceed 30 U/kg of body weight (Lowe et al., 2007).

Particular attention should be given to children with severe forms of cerebral palsy, including GMFCS levels IV–V (Langdon et al., 2010). The U.S. The Food and Drug Administration (FDA) has expressed specific concerns regarding the risk of respiratory failure in this group of patients. These patients require more rigorous monitoring because of the higher chance of systemic complications (Friedman and Goldman, 2011).

To avoid the development of secondary resistance to treatment, it is necessary to maintain a minimum three-month interval between sessions (Mirska et al., 2019). Excessive frequency of administration may lead to the formation of neutralizing antibodies against the toxin, which completely eliminates the therapeutic effect (Placzek et al., 2010). Studies also show that less frequent injections, for example, once a year, may be equally effective to the more frequent regimens, while having a lower risk of adverse effects and muscle atrophy (Multani et al., 2019).

Summary

A total of 22 studies were included in this systematic review. The studies consistently demonstrate that BoNT-A is an effective and safe treatment for spasticity in children with CP. The following table provides a summary of selected studies described in the sources we used while writing the paper. We focused on patients' characteristics, the treatment administered, efficacy outcomes, and reported adverse events. The results are summarized in Table 2.

Table 2. Summary of included studies on BoNT-A treatment in children and adolescents with Cerebral Palsy.

Study / Author	Patients (N) / GMFCS	Muscles / Dosage	Efficacy - main results	Adverse Events (AE)
Lundy et al., (2009)	N=26, GMFCS V (non-ambulant)	Adductor magnus, medial hamstrings, iliopsoas; Avg 12 U/kg Botox	Highly significant improvement in pain scores at 3 months and improved quality of life.	No significant side effects reported.
Terebessy et al., (2019)	N=30, GMFCS I-V	Triceps surae, multilevel lower limb; Max 8 U/kg	Improved range of motion (ROM) and decreased muscle tone/spasticity. Gait analysis showed little change.	Nausea/vomiting (3), rash (1), generalized lower limb muscle weakness (2).
Mirska et al., (2019)	N=60, GMFCS I-V	Gastrocnemius and soleus; Avg 13.2 U/kg Dysport	Effective regardless of the number of sessions. Maximum improvement seen at 3 months.	Therapy considered safe when repeated every 3-6 months.
Boudokhane et al., (2025)	N=55, GMFCS I-V	Triceps sural, adductors; Avg 2 U/kg Botox	Significant reduction in MAS Scale scores from 2.1 to 1.0.	AEs in 16 children (29.1%) such as weakness, flu-like symptoms, 1 case of "botulism-like" syndrome.
Hong et al., (2017)	N=144, GMFCS I-III	Triceps surae; 6 U/kg (bilateral) or 4 U/kg (unilateral)	First injection improved motor function significantly more than repeated ones at 12 weeks.	Safety profiles of letibotulinumtoxin A and onabotulinumtoxin A were similar.
Tedroff et al., (2009)	N=94, GMFCS I-V	Gastrocnemius, hamstrings, adductors; Median 2 injections per muscle	Long-term spasticity reduction, but failed to prevent contractures as ROM declined after initial gains.	Excessive weakness or painful injections in 4% of patients.
Lowe et al., (2007)	N=42, GMFCS I (upper limb)	Avg 7.4 - 7.6 U/kg Botox (repeat injections)	Improvements in arm movement and functional skills maintained over 30 months.	55 AEs total (mostly respiratory infections); none directly linked to BoNT-A.

Schasfoort et al., (2018)	N=65, GMFCS I-III	Multilevel; Max recommended doses	BoNT-A added to intensive physiotherapy (PT) provided no extra functional benefit over intensive PT alone.	No serious side effects; complications mainly related to casting or orthoses.
Bjornson et al., (2007)	N=33, GMFCS I-III	Gastrocnemius; 12 U/kg Botox vs Saline placebo	Reduced spasticity and improved motor function at 6 months.	56 total AEs; no significant difference in frequency between BoNT-A and placebo groups.
Camargo et al., (2009)	N=20, spastic diplegia	Triceps surae, adductors; Avg 7.45 U/kg Botox	Improved walking and gait patterns; structural foot changes sustained, but functional gains were temporary.	Lower limb weakness in 3 patients; one reported fall.

The evidence shows that BoNT-A is a standard in the management of spasticity in CP. In multiple studies, repeated injections have reduced muscle tone, improved gait parameters, enhanced upper limb function, and provided meaningful pain relief. What's important is that the studies show that BoNT-A should not be used in isolation. The combination of BoNT-A with intensive physiotherapy, occupational therapy, and orthotics consistently has better outcomes than either of these interventions alone. Treatment goals have to be proper for each patient's GMFCS level. For patients at GMFCS I-III, the aim is gait improvement, but for GMFCS IV-V, we focus on pain relief and quality of life enhancement.

Information in the included studies confirms that BoNT-A is a well-tolerated medicine. The most serious concern is the risk of respiratory complications in children with severe CP (GMFCS IV-V). That necessitates careful dosing and monitoring.

4. CONCLUSION

Botulinum toxin type A continues to be a standard treatment for spasticity, improving function and quality of life in children with cerebral palsy. The effectiveness of this therapy depends on setting realistic and achievable goals, precise injection technique, and combining intensive physiotherapy and orthotic management. However, treatment should be individualized, thinking about the potential long-term impact on muscle structure. That requires careful planning of each therapeutic cycle by clinicians and physiotherapists. While the treatment is well-tolerated, it is essential to maintain a minimum interval of three months between sessions. Ultimately, regular BoNT-A use can delay or reduce the need for invasive surgical procedures and significantly enhance the overall quality of life for both patients and their caregivers.

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All authors have read and agreed with the published version of the manuscript.

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Conflict of interest
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Data and materials availability
All data associated with this study will be available based on the reasonable request to corresponding author.

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