

Botulinum Toxin (A) Versus Topical Anesthesia for Spasticity Control in Hemiplegic Cerebral Palsied Children

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ABSTRACT

Purpose: The aim of the present study was to compare the possible effects of Botulinum toxin (BT-A) and topical anesthesia (TOPA) on muscle tone and motor control of the lower extremities in hemiplegic cerebral palsied children. **Methods:** Thirty cases of ambulant spastic hemiplegic cerebral palsied children (19 males, 11 females) with (mean age 4 y and 5 months \pm 1 y and 4 months, range 3 to 7 years) were studied. Subjects were divided into two groups equal in numbers: (1) BT-A group received two successive doses of BT-A injection to the calf muscles with two successive months interval between the two doses. (2) TOPA group received local anesthesia (EMLA cream) for the calf muscles, three times per week for a three successive month's period. Muscle tone assessment, ankle dorsiflexion range, and gait evaluation were conducted for every child in BT-A and TOPA groups at entry and after the treatment course for each group. **Results:** A comparison between BT-A and TOPA groups showed (1) Significant improvement in Ashworth scale, Tardieu scale, step width, and passive ankle dorsiflexion range in favor of the BT-A group. (2) Significant improvement in foot angle and active dorsiflexion range in favor of the TOPA group. **Conclusion:** Children with hemiplegic CP revealed improvements in muscle tone, range of motion, and gait parameters after BT-A or topical anesthesia. BT-A was shown to be of almost similar efficacy to topical anesthesia in respect to improvement in gait parameters. Additionally, tone reduction was more with BT-A injection, while improvement of active dorsiflexion range was more with topical anesthesia.

Key words: Cerebral palsy; Botulinum toxin; topical anesthesia; spasticity; gait.

INTRODUCTION

Cerebral palsy (CP) is the commonest cause of severe physical disability in childhood, affecting 1 in 400 children¹. It consists of a heterogeneous group of motor disorders including spasticity, paresis, incoordination, and dystonia. Eighty per cent of these children have problems with walking as a result of lower limb spasticity², which can lead to severe contractures and limb deformity. Severe spasticity frequently results in abnormal postures and may also interfere with voluntary movements and lead to functional disability³.

Spasticity has been defined as "a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex, as one component of the upper motoneuron (UMN) syndrome"⁴. In other words, spasticity and flexor spasms of UMN syndrome are due to hyperactive spinal reflexes. Some hypertonus of the UMN syndrome is due to imbalance in descending motor control⁵.

Conventional treatment is based around physiotherapy^{6,7}, orthoses, and walking aids, none of which produce long-lasting results⁷. However despite these therapies, many children require corrective surgery for

deformity. The use of systemic antispasticity treatments such as baclofen, although effective, is limited by side effects such as drowsiness and generalized muscle weakness⁸. Destructive treatments using phenol nerve blocks, which can cause sensory loss⁹, are inappropriate in the management of children who have a maturing nervous system³.

Botulinum toxin (BT-A) is a potent neurotoxin that is synthesised by the anaerobic bacterium *Clostridium botulinum*. The toxin blocks the release of acetylcholine at the neuromuscular junction¹⁰. The clinical effect of BT-A on motor function is observed within a few days of an intramuscular injection and usually lasts 3-4 months. It produces a local, temporary weakness that is associated with a decrease in muscle stiffness (spasticity)¹¹. It is thought that decreasing the spasticity will allow for better stretching of the shortened muscles, increased range of motion and opportunities to strengthen muscles that work opposite to the muscle that has been injected. These changes should allow the children to learn better control their movement and to improve their motor function¹². Restoration of neurotransmission starts with the formation of new synaptic connections with the intact neurones in the vicinity of the affected nerve terminals (collateral sprouting) and is fully accomplished when recovery of the affected nerve terminals (regenerative sprouting) is completed¹¹.

Numerous studies have investigated the cutaneous receptors of the lower limbs with respect to reflex modulation and integration within the central nervous system. Topical anaesthesia has been used to reduce cutaneous inputs¹³⁻¹⁷ with varying results, ranging from no effect on motoneuron excitability in normal subjects¹⁶ to increased joint range during gait in a patient following stroke¹³. Similarly, when cutaneous inputs were increased using

transcutaneous electrical nerve stimulation. Arsenault et al.,¹⁶ and Goulet et al.,¹⁸ reported no effect on normal motoneuron excitability, whereas Levin and Chan¹⁹ and Seib et al.,²⁰ demonstrated reduced spasticity in subjects with neurological deficits.

The aim of the present study was to compare the possible effects of Botulinum toxin (BT-A) and topical anesthesia (TOPA) on the muscle tone as well as the motor control of the lower extremities in spastic hemiplegic cerebral palsied children. Ankle dorsiflexion range of motion and gait pattern were used as indicators for lower extremities control.

MATERIAL AND METHODS

Subjects

Thirty cases of ambulant spastic hemiplegic cerebral palsied children (19 males, 11 females) (with mean age 4 y and 5 months \pm 1 y and 4 months, range 3 to 7 years) were studied. Subjects were invited regardless the cause of cerebral palsy. The degree of spasticity of all subjects was ranged from grade 1 to grade 3 (i.e mild to moderate spasticity) according to modified Ashworth²¹ scale. All could walk with or without walking aids. The children recruited had dynamic equinus with an inability to achieve heel strike because of lower limb spasticity predominantly affecting the calf muscles. None had received Botulinum toxin injection or topical anesthesia previously and all had received conventional treatment with physiotherapy and foot orthosis. Children who had fixed contractures or previous surgery to the lower limb were excluded. Subjects divided into two equal homogenous groups. BT-A group received Botulinum toxin (Type A) injection to the calf muscles, while TOPA group received a mixture of local anesthesia (EMLA cream) for the calf muscles. Subjects

were assigned randomly to each group by flipping a coin. Informed consent was obtained prior to the study.

Procedures

Treatment

Botulinum toxin (Type A): BT-A Group received two successive doses of BT-A (BOTOX, Allergan, USA) to the affected gastrocnemius and soleus at two months interval. BT-A was made up to a standard concentration according to the manufacturer's instructions (200 U/ml of 0.9% saline), resulting in a relatively small volume of injection and thus limiting pain from stretching the muscle capsule. BT-A was administered using a 27 gauge needle into the gastrocnemius and soleus muscle groups. Lateral and medial gastrocnemius muscles were injected with a mean dose of 75 U BT-A for each muscle. Soleus was injected with a mean dose of 50 U BT-A. We identified the target muscles by clinical examination and no sedation was used for injections although the injection sites were numbed with ice spray.

Topical anesthesia: A mixture of local anesthetics (EMLA 5%), which consists of lignocaine and prilocaine (25mg/g) was used for TOPA group. This mixture produces effective topical anesthesia of the intact skin with minimal side effects²². The EMLA cream was applied to the entire soles of the feet and the undersurface of the toes. An elastic bandage was wrapped in a figure of eight pattern around the subject's feet; the bandage applies compression and heat that enhances the penetration of EMLA. Subjects rested in sitting for 60 minutes with their feet elevated on a foot stool. EMLA was used three times weekly basis (every other day) for 3 successive month's period.

Both groups received a well designed physical therapy program, one hour for each patient,

three times weekly basis (every other day) over the three month's period. This therapeutic exercise program primarily included: muscle stretching of the achillis tendon; facilitation of ankle dorsiflexors; training of walking and up/down stairs.

Evaluation

The following evaluation protocol of tone assessment, ankle dorsiflexion range, and gait evaluation were conducted for every child in BT-A and TOPA groups at entry, after three successive month's period for TOPA group, and one month after the last injection dose for the BT-A group.

Muscle tone assessment:

The degree of spasticity was measured according to:

1. Adjusted Ashworth²¹ scale It is measured by the average degree of resistance exhibited to passive dorsiflexion movement for the affected lower limb. The modified Ashworth scale (MAS) for spasticity as published is scored 0–4, with a 1+ grade as follows (0, 1, 1+, 2, 3, 4), but for data analysis the scores were adjusted to give a 0–5 score range (0, 1, 1+ became 2, 2 became 3, 3 became 4, and 4 became 5) appendix 1.
2. Modified Tardieu test²³ was used to measure the joint range of motion during fast passive movement of the joint (velocity-dependent component of spasticity). The muscle was stretched quickly to provoke the velocity dependent increase in muscle tone typically for spastic hyperactivity. "The test begin with the relaxed muscle during the initial phase of fast passive movement, the muscle does not show any or only minimal resistance in muscle tone. This initial phase is followed by a sudden (catch) a sudden resistance to fast passive stretch typical for spastic hyperactivity. The earlier this catch occurs;

the more hyperactive is the muscle" appendix 2.

Gait assessment:

The motor function of the affected side was assessed via evaluating four major gait parameters. These parameters are: affected step length, unaffected step length, step width, and foot angle. Pedograph, as a physical therapy tool for gait evaluation, was used.

The pedographs were performed in a room with a walkway approximately 15 meters in length and sufficient space to manage the activity. The paper was premeasured into 10-meter lengths and taped to the floor. The procedure was described to the child, who watched other children doing the pedographs. One practice walk was used to familiarize the child with the procedure. Water-soluble block-printing ink was then applied to the bottoms of

the feet with a brayer (an art tool used for applying ink to block-prints). The child was helped to stand and stood still for a few seconds, which provided a good print of both feet before starting to walk. The child then walked the length of the paper. Perpendicular lines were drawn one meter from the beginning and end of the paper and these two parts were excluded.

Ankle dorsiflexion range of motion

The mean active and passive ankle dorsiflexion ranges of the affected side were measured using a protractor goniometer with the knee in maximum extension. A right angle between the fibula shaft and the fifth metatarsal bone was defined as 0° of dorsiflexion. The angle between the fibula shaft and the fifth metatarsal bone was measured after active and passive dorsiflexion.

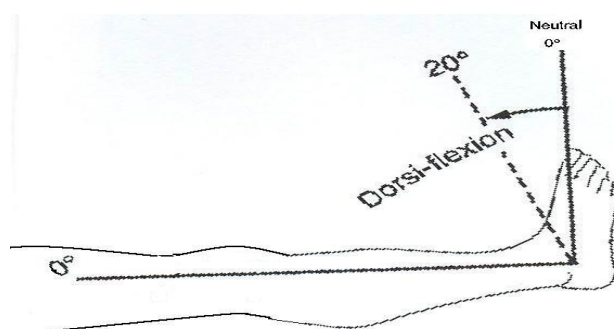


Fig. (1): Measurements of ankle dorsiflexion range of motion.

Statistical Analysis

The collected data was statistically treated to show the mean, range, standard deviation and standard error for all sets of measurements, before and after the treatment courses in both groups (BT-A and TOPA). Paired t-test was conducted to compare between results collected before and after treatment for each treatment group. Independent t-test was conducted to compare

between the results in both groups BT-A and TOPA before and after the treatment course. P-value <0.05 will be considered significant.

RESULTS

Fifteen spastic hemiplegic CP children received BT-A (M/F 9/6, mean age 4 y and 5 months \pm 1 y and 5 months, and mean weight 19.6 \pm 3.7) and 15 received topical anesthesia

(M/F 10/5, mean age 4 y and 4 months \pm 1 y and 3 months, and mean weight 19.8 ± 4.1).

Muscle tone

Significant improvement was observed in Ashworth and Tardieu scores after BT-A injection ($P = 0.000$, $P = 0.001$ respectively)

while only Ashworth score was improved after TOPA ($P = 0.000$, $P = 1.00$ respectively). A comparison between BT-A and TOPA showed significant improvement in Ashworth and Tardieu scales in favor of the BT-A group ($P = 0.002$, $P = 0.001$ respectively) (Table I, Figure 2).

Table (1): Measurements of muscle tone in BT-A and TOPA groups before and after the treatment courses.

Variables		BT-A Group			TOPA Group			^b P
		Pre	Post	^a P	Pre	Post	^a P	
Ashworth scale	Mean (SD)	3.1 ± 1.1	1.5 ± 0.5	0.000*	3.2 ± 0.9	2.4 ± 0.9	0.000*	0.002*
Tardieu scale	Mean (SD)	3.1 ± 1.0	2.1 ± 0.6	0.001*	3.1 ± 0.7	3.1 ± 0.6	1.000	0.000*

^a Difference tested with paired t-test between the pre and post measurements for each group.

^b Difference tested with independent t-test between BT-A and TOPA groups for the post measurements.

* Values significant at $p < 0.05$.

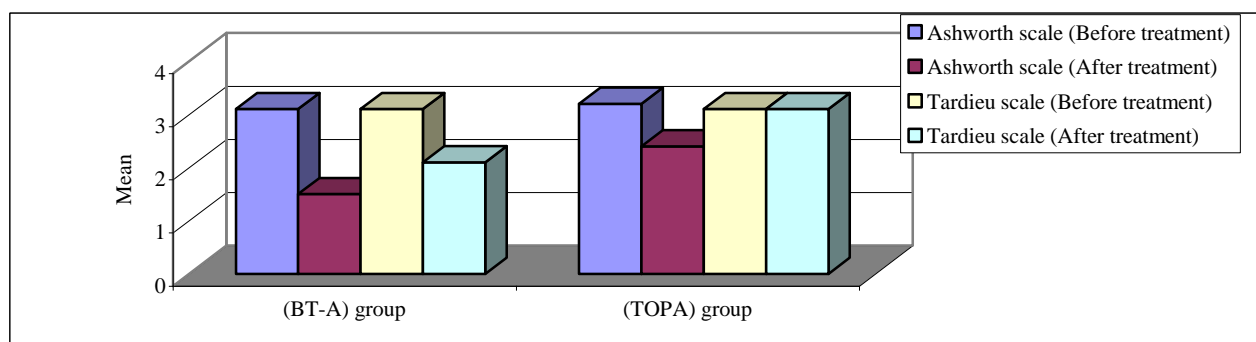


Fig. (2): Comparison between measurements of muscle tone before and after treatment in both groups.

Gait parameters

All gait parameters were significantly improved following BT-A and TOPA, except for the affected step length that was showed no improvement after TOPA ($P = 0.36$). A comparison between BT-A and TOPA showed significant reduction in the affected foot angle

in favor of the TOPA group ($P = 0.04$) and step width in favor of the BT-A group ($P = 0.007$) (Table II, Figure 3). No significant difference was detected between both groups in respect to the affected and none affected step lengths ($P = 0.23$, $P = 0.24$ respectively).

Table (2): Measurements of gait parameters in BT-A and TOPA groups before and after the treatment courses.

Variables		BT-A Group			TOPA Group			^b P
		Pre	Post	^a P	Pre	Post	^a P	
None affected step length	Cm mean (SD)	33.7±5.6	38.4±4.6	0.000*	31.4±5.6	36.9±5.4	0.000*	0.428
Affected step length	Cm mean (SD)	36.0±6.4	38.5±5.3	0.000*	35.8±5.6	36.1±5.8	0.364	0.236
Affected foot angle	mean (SD)	11.7±5.5	7.7±4.4	0.000*	11.3±5.2	5.1±2.0	0.000*	0.04*
Step width	Cm mean (SD)	11.8±5.0	5.3±1.8	0.000*	12.0±5.1	8.8±4.3	0.000*	0.007*

^a Difference tested with paired t-test between the pre and post measurements for each group.

^b Difference tested with independent t-test between BT-A and TOPA groups for the post measurements.

* Values significant at $p < 0.05$.

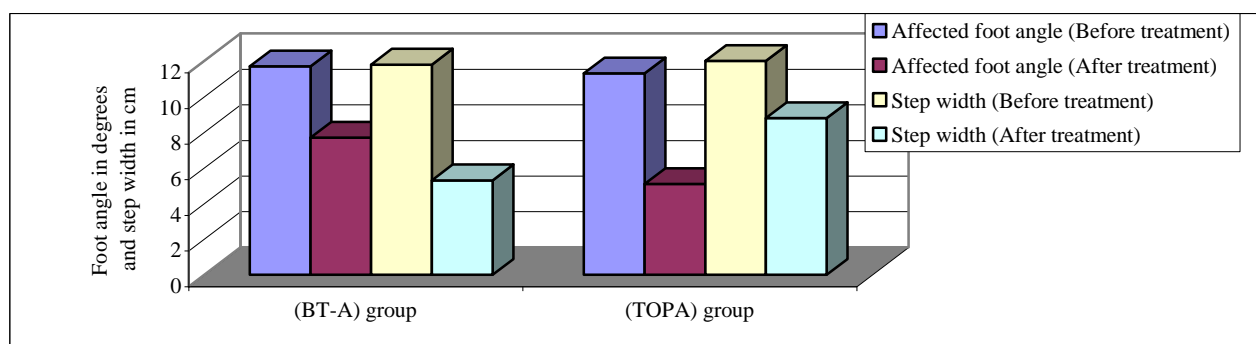


Fig. (3): Comparison between measurements of the affected foot angle and the step width before and after treatment in both groups.

Ankle dorsiflexion range

Results showed significant improvement of both active and passive dorsiflexion ranges following BT-A and TOPA treatment. On comparing between both groups, passive

dorsiflexion range was increased significantly in favor of the BT-A group ($P = 0.007$) while active range was increased significantly in favor of the TOPA group ($P = 0.006$) (Table III, Figure 4).

Table (3): Measurements of ankle dorsiflexion ranges in BT-A and TOPA groups before and after the treatment courses.

Variables		BT-A Group			TOPA Group			^b P
		Pre	Post	^a P	Pre	Post	^a P	
Active dorsiflexion range	Mean (SD)	5.1±3.9	6.3±4.0	0.008*	4.7±4.2	10.4±3.5	0.000*	0.006*
Passive dorsiflexion range	Mean (SD)	10.4±6.3	16.4±3.7	0.000*	9.5±5.1	12.3±4.0	0.000*	0.007*

^a Difference tested with paired t-test between the pre and post measurements for each group.

^b Difference tested with independent t-test between BT-A and TOPA groups for the post measurements.

* Values significant at $p < 0.05$.

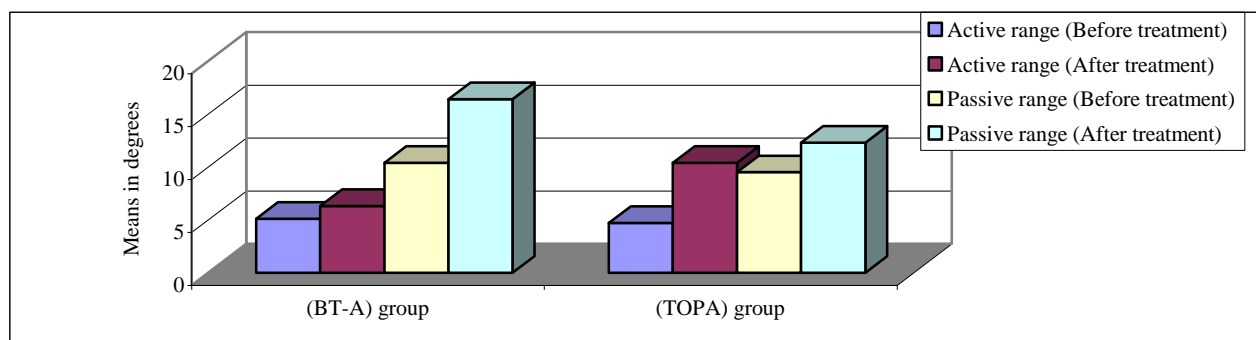


Fig. (4): Comparison between measurements of active and passive ankle dorsiflexion range before and after treatment in both groups.

DISCUSSION

The entry level measurements of gait parameters revealed unequal and decreased step lengths (affected and unaffected), more decrease in the unaffected step length, out-toeing or in-toeing (Increased foot angle), and increased step width. Abnormal postural tone which restricts the child's walking is considered the main cause for these deviations^{24,25}. Furthermore, Gage² showed that appropriate gastrocnemius length is necessary for adequate ankle dorsiflexion in swing and at initial contact in stance. Patients without adequate gastrocnemius length demonstrate gait deviations. Results of the current study showed improvement in almost all gait parameters in children with hemiplegic CP received BT-A or topical anesthesia targeted at the calf muscles. The affected foot angle was significantly reduced with TOPA more than with BT-A and this could be attributed to the greater improvement of active ankle movement observed in TOPA group. On the other hand, step width was significantly reduced with BT-A more than with TOPA which might be due to the more tone reduction obtained in BT-A group.

In agreement with our results, a number of studies have reported improvement in walking following BT-A therapy. Cosgrove et al.,²⁶ studied 26 children with leg spasticity caused by cerebral palsy; 14 showed notable functional improvement following BT-A treatment. Koman et al.,²⁷ originally reported improvement in the Physician's Rating Scale in six children randomized to receive BT-A compared with six children who received placebo. In their most recently published study, Koman et al.,²⁸ showed improvement in gait function and partial denervation of the injected muscle as part of a larger multicentre trial. Sutherland et al.,²⁹ reported significant improvement in ankle dorsiflexion while walking following BT-A treatment.

Adverse events relating to botulinum toxin were mild and transient such as flu like symptoms and weakness of muscles adjacent to the site of injection; this was in accordance with previous published reports^{24, 30}. Major adverse effects and systemic botulism were uncommon.

Little was found about the use of topical anesthesia in children with CP. Sabbahi et al.,¹³ applied topical anesthesia to the skin of the leg and thigh of a hemiparetic patient. They found a substantial shift of angular displacement of ankle and knee joints,

measured during a full gait cycle, towards its normal value. This response indicated a reduction in muscle spasticity which was confirmed by clinical tests. Katz³¹ reported that topical anesthesia may decrease reflex activity for short periods of time in order to facilitate minimal motor function. Also, our clinical findings of TOPA group revealed significant reduction of spasticity however; more reduction was noted in BT-A group and this was explained by the neuromuscular blockade effect of the botulinum toxin as well as inhibition of the fusiform system and muscle spindle^{12,32}. Neurophysiologic studies revealed that the reduction in muscular hypertonicity following topical anesthesia was mediated by reduced cutaneous inputs on the alpha-gamma motoneuron interaction. This conjecture is supported by studies of other investigators performed on animals as well as humans^{13,14}.

Reduction in calf muscle spasticity would improve passive ankle dorsiflexion range as shown in open studies^{26, 28} and this was recorded in our results contradicting earlier findings of Sutherland et al²⁹ who recorded a positive effect for BT-A on foot placement in spite of lack of the effect on passive movement. It is important to mention that improvement of passive dorsiflexion range was higher in BT-A group than in TOPA group, while improvement in active range was higher in TOPA group than in BT-A group.

Due to lack of control of all variables, the results of this study do not provide conclusive evidence of the efficacy of BT-A or topical anesthesia. However, this study and our clinical observations do suggest that children with hemiparetic CP are able to achieve muscle tone, range of motion, and gait improvements after BT-A or topical anesthesia. BT-A was shown to be of almost similar efficacy to topical anesthesia in respect

to improvement in gait parameters. Additionally, tone reduction was more with BT-A injection, while improvement of active dorsiflexion range was more with topical anesthesia. Of interest would be comparison of long-term muscle tone and gait improvements in the patient population receiving BT-A or topical anesthesia with patients not receiving these interventions. Investigation of long-term outcomes would provide beneficial information to physicians and therapists treating patients with spasticity.

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Appendix (1): Adjusted Ashworth scale²¹ for grading spasticity.

Grade	Description
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part (s) is moved in flexion or extension.
2	Slight increase in muscle tone, manifested by a catch, followed by a minimal resistance throughout the remainder (less than half) of the range of motion ROM.
3	More marked increase in muscle tone through most of the ROM, but affected part (s) easily moved.
4	Considerable increase in muscle tone, passive movement is difficult.
5	Affected part (s) rigid in flexion or extension.

Appendix (2): Modified Tardieu test²³ (Resistance to fast passive stretch).

Grade	Description
1	Slight resistance throughout passive movements with no clear catch at any specific angle.
2	Passive movement is interrupted at specific angle by clear catch followed by release.
3	Fatigue (clonus) less than 10 seconds when maintaining the pressure, appearing at specific angle.
4	Indefatigable clonus (more than 10 seconds) when maintaining the pressure appearing at specific angle.
5	Joint is rigid

الملخص العربي

سم البوتولينوم (أ) مقابل التخدير السطحي للتحكم في التصلب لدى أطفال الشلل الدماغي النصفي

تهدف هذه الدراسة إلى بيان ومقارنة التأثيرات المحتملة لسم البوتولينوم (أ) والتخدير السطحي على النغمة العضلية والتحكم الحركي في الطرف السفلي لدى الأطفال المصابين بالشلل الدماغي النصفي . أجريت هذه الدراسة على 30 طفل من مرض الشلل الدماغي النصفي التصلبي تتراوح أعمارهم ما بين 3 إلى 7 سنوات . قسمت عينة الدراسة عشوائياً إلى مجموعتين متساويتين ومتجانستين . تم حقن أطفال المجموعة الأولى بجرعتين من سم البوتولينوم في عضلات السمانة. تم حقن الجرعة الثانية بعد مرور شهرين من الجرعة الأولى. في حين تم تطبيق برنامج من التخدير السطحي لأطفال المجموعة الثانية على عضلات السمانة ، ثلاث مرات أسبوعياً ، لمدة ثلاثة أشهر . علماً بأنه لم يتوقف تطبيق برنامج العلاج الطبيعي العادي لأطفال المجموعتين . تم قياس النغمة العضلية والمدى الحركي الإرادي واللاإرادي لثني مفصل الكاحل وكذلك فحص نمط المشي لجميع أفراد العينة قبل العلاج وبعد ثلاثة أشهر من بدأ العلاج . أشارت النتائج لوجود فروق ذات دلالة إحصائية قبل وبعد العلاج في كلا من المجموعتين وذلك في جميع المتغيرات التي تم تقييمها. وعند مقارنة نتائج ما بعد العلاج في مجموعة البوتولينوم بمثيلتها في مجموعة التخدير السطحي تم استنتاج ما يلي : (1) هناك فروق ذات دلالة إحصائية في تحسين النغمة العضلية والمدى الحركي الإرادي واتساع الخطوة وذلك في صالح مجموعة البوتولينوم ، (2) هناك فروق ذات دلالة إحصائية في تحسين المدى الحركي الإرادي وزاوية انحراف القدم وذلك في صالح مجموعة التخدير السطحي . وعليه يمكننا أن نستنتج أن كلا من سم البوتولينوم والتخدير السطحي لهما تقريباً نفس التأثير في تحسين نمط المشي لدى أطفال الشلل الدماغي النصفي التصلبي في حين كان سم البوتولينوم أفضل في تحسين النغمة العضلية وكان التخدير السطحي أفضل في تحسين المدى الحركي الإرادي عند هؤلاء الأطفال .