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Comparative Study of Two Different Treatment Methods in Children with Idiopathic Tip-Toe Walking

KEYWORDS: Idiopathic tip-toe; Gait parameters;Functional activity; Botox

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ABSTRACT *Idiopathic toe-walking is a persistent toewalking in children older than 3 years of age in the absence of developmental, neurological or neuromuscular conditions.So, The purpose of this study was to compare the effects of Botox injection and a designed physical therapy program on gait parameters and functional activity of children with idiopathic tip-toe walking. Forty-five children of both sexes with age ranged from 3 to 5 years were selected. They were assigned randomly into three groups of equal number. Group I received a designed physical therapy program, group II received Botox A injection of bilateral calf muscles and the same physical therapy program given to group I ,while group III received Botox injection of bilateral calf muscles only. Gait parameters including (stride length, velocity and cadence) and the functional activity were measured before treatment, after 3 months of treatment (post 1), after 6 months of treatment (post2).After three months of treatment, significant differences were recorded in all measuring variables in group II, III in favor of group II, while non-significant difference was observed in group I. After six months, significant differences were recorded in group I, II in favor of group II. While non-significant improvement was observed in group III. Therefore,Botox injection of the calf muscle together with a selected physical therapy program is an excellent decision for correcting idiopathic tip-toe walking in children*

1-Introduction

During normal childhood independent standing and walking are achieved on average 9.5 and 13 months respectively. Toe-walking is not usual or a predominant feature in early stages of development. Initially the child ambulates with the feet wide apart to provide a stable base for a relatively high center of gravity. Initial foot strike occurs with the ankle in plantarflexion but gradually develops into ankle dorsiflexion and heel-strike **[1]**.This is usually completed by the age of five**[2]**.Toe-walking is a pretty common gait deviation in children which is considered normal up to three years old of age**[3]**.Idiopathic toe walking (ITW) is a diagnosis that can only be made in the absence of any medical condition known to cause toe walking and presents in either gender **[2]**.It has been estimated to occur in 7% to 24% of the children population **[4]**. Several causes of tip toe walking have been suggested, such as delayed development of the cortico-spinal tract [5] vestibular dysfunction **[6]**, congenital short Achilles tendon**[2]** , and even being part of normal gait development **[7]**. Premature onset of gastrocnemius activity prior to foot contact and continuing into stance phase was found when electromyographic studies were applied with inhibition of tibialis anterior in swing phase. Normally tibialis anterior is active at heel-strike and during stance. Gastrocnemius onset occurs to produce plantarflexion and take-off. Tibialis anterior concentrically contracts controlling dorsiflexion at swing phase by allowing heel-strike, then eccentrically contracts to facilitate plantarflexion along with gastrocnemius **[8]**.In most cases, idiopathic toe-walkers are able to strike the floor with the heel, but they choose forefoot contact instead. Such a choice could be also due to a more comfortable ankle position [7].Excessive ankle plantarflexion affects the child's pattern of gait and disables his ability for functional play, such as all symmetrical bilateral coordination activities **[9]**. A relationship has been reported between persistent toe walking and the development of ankle equinus [10]. A variety of treatment recommendations have been suggested for ITW, such as physiotherapy, serial casting **[2]**, and open or percutaneous lengthening of the Achilles tendon, but the treatment results have been questioned [11]. Casting does appear to benefit idiopathic toe walkers in the short-term by improving ankle dorsiflexion and stopping toe-walking in the majority of cases [2]Other studies, however, have shown no long-term effect of cast treatment [12]. Botox A was first introduced for pediatric use in patientswith spasticity, typically associated with cerebral palsy, in the early 1990s. Subsequently, the suggested indications for Botox A have expanded **[13]**. Botox treatment has also been introduced in children with ITW. The reported results from two pilot studies on children with ITW, one study on fivepatients [8]and another, in which a combination of Botox, casting, and bracing were used, indicate a promising effect, but there is still a need for results from a larger patient population and over a longer follow-up period [14].. In recommended doses, Botox is completely safe with a very low complication rate. There have been reports of local complications, including pain at the injection site and local muscle weakness, but it is always temporary, lasting up to a few weeks **[5]**.

So, the purpose of this study was to compare between the effects of Botox injection and a designed physical therapy program on gait parameters and functional activity of children with idiopathic tip-toe walking.

2. Subjects, randomization and methods

2.1 Subjects

Volume : 4 | Issue : 12 | Dec 2014 | ISSN - 2249-555X

All children with the preliminary diagnosis of bilateral ITW, in the Paediatric Orthopaedic Clinic of Abu-El Reesh Hospital for Pediatrics, National Institute for Neuro-Motor System and Police Hospital at Agouza between December 2009 and September 2013, were invited to participate in a prospective study. The child's preliminary exclusion included children with known neuromuscular disorders, neurological condition, other known orthopedic problems, previous treatments such as Achilles tendon surgery, casting, and Botox injection. At the initial visit, the child's birth history, family history and motor development were reviewed. Specifically, parents were questioned about the age of independent walking, the use of a baby walker, and the age at which toe-walking was first noticed. The presence of pain, balance, shoe wear problems and difficulties were noted. Each child underwent a full neurological examination by a pediatrician specifically looking at: 1) muscle bulk 2) tone, 3) sensation, 4) deep tendon reflexes and 5) Gower's test. In addition to full orthopaedic examination of the spine, hips, legs and feet was performed assessing range of movement, alignment and laxity.

Forty-five children from both sexes between the ages of 3 and 5 years were recruited to participate in this study. Their height ranged between 92 and 107 cm and their weight ranged from 14 to 18 kilogram (kg). They were selected with inclusion criteria including: they were able to walk independently but on tip toe with repetitive falling. They had sufficient cognition and were able to understand commands given to them. They had mild to moderate tightness of the calf muscles. Muscle testing of anterior tibial group was sub-functional with full passive range of motion (ROM) of the ankle dorsiflexion either with the knee flexed or extended for both lower limbs. Children with one or more of the following criteria were excluded from the study: children with medical conditions that would severely limit a child's participation in the study as vision or hearing loss, cardiac anomalies, previous history of fracture,presence of subluxation, infection, or any other conditions that could affect the anatomical structures.

The children were randomly assigned into three groups of equal number: group I (7 boys and 8 girls), group II (8 boys and 7 girls) and group III (8 boys and 7 girls). All procedures involved for evaluation and treatment, purpose of the study, potential risks and benefits were explained to all children and their parents. This work was carried out in accordance with the code of Ethics involving humans.The study was approved by an Ethical Committee of the Cairo University.Parents of the children signed a consent form prior to the participation.

2.2 Randomization

Fifty-five children were assessed for eligibility. Eight children were excluded as they did not meet the inclusion criteria, and two children were excluded as their parents refused to participate in the study. Following the baseline measurements, randomization process was performed using closed envelopes. The investigator prepared 45 closed envelopes with each envelope containing a card labeled with either group I, II or III. Finally, each child was asked to draw a closed envelope that contained one of the three groups, figure (1).

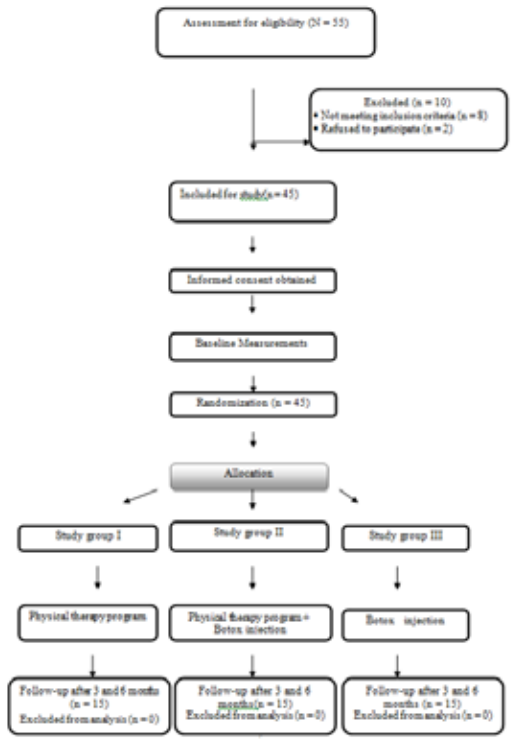

Figure 1.Flow chart showing the experimental design of the study

2.3. Methods

2.3.1. For evaluation

Gait parameters and the functional activity were measured by using three dimensional (3-D) gait analysis and Peabody Developmental Motor Scale-version 2 (PDMS-2) respectively. The evaluation was done before, after 3 months of treatment (post 1), follow-up after 6 months (post 2). All procedures were explained to the parents and their children.

2.3.1.1 Gait analysis

All children underwent 3-D gait analysis using six-camera system (Vicon, Oxford, UK) with reflected markers placed on anatomical landmarks. Kinematic markers were fixed with double-sided tape and placed bilaterally over the anterior superior iliac spine, the point midway between the 2 posterior superior iliac spines, the lateral epicondyle of the femur, lateral shank, lateral malleolus, heel, and between the distal second and third metatarsal head **[15]**. At first, certain parameters were fed to the device (Child's age, height and weight which were measured by weight and height scales). On each test, the child was asked to walk barefoot at a self-selected and comfortable speed along eight meters walkway. Gait parameters including: stride length (meter), velocity (meter/second) and cadence (steps/minute) were analyzed.

2.3.1.2. Peabody Developmental Motor Scales-version 2:

The Peabody Developmental Motor Scale version 2 (PDMS-2) can be used to estimate a child's overall competence relative to peers, or to evaluate his or her gross motor abilities**[16].**Standardized tests have permitted therapists and other professionals to assessment [17]. Evaluation of the gross motor

Volume : 4 | Issue : 12 | Dec 2014 | ISSN - 2249-555X

scale (locomotion) of the children was carried out for each child in the three groups individually. The child was in a comfortable position and received clear explanation about the procedures of the test **[16].**

Scoring Criteria:The PDMS-2 is based on scoring each item as 2, 1, and 0.The examiner must decide how to score the item based on her judgment of the child's performance and specific criteria for each item. The general criteria for scoring items are presented in table 1.

Table 1.criteria for scoring of PDMS-2

Score	Description of performance
2	The child performs the item according to the criteria specific for mastery.
1	The child performance shows a clear resemblance to the item mastery criteria but doesn't fully meet the criteria.
0	The child cannot or will attempt the item, or the attempt doesn't show that skill is emerging.

2.3.2. Treatment protocol

Group I: The children in this group received a designed physical therapy program. The program consisted of gentle stretching exercises of the calf muscles, facilitation of muscle contraction for the anterior tibial group muscles, proprioceptive training, balance and postural control exercises, neurodevelopmental techniques and gait training. The total program lasted for 1 hour/three times per week for successive six months.. The parents were instructed to wear their children medical shoes.

Group II: All children in this group were injected in bilateral calf muscles with Botox A (Allergan, USA) . Neuro-pediatric specialist injected the children bilaterally with a total of 6 units/kg of bodyweight. One hour before the injection, all children were given oral paracetamol (40 mg/kg) and a topical anesthetic cream was applied at the injection sites. Four injection sites in each calf, two in the proximal third of the lateral and medial gastrocnemius bellies and two distally in the gastrocnemius–soleus complex, were administered **[18]**. After the injection, the parents were instructed to use rigid AFOs for 23 hours per day for two successive weeks to maintain the flexibility that has been gained with previous treatment by Botox[19]After that, the parents instructed to wear their children medical shoes. In addition to the same designed physical therapy program which was given to the children in group I. The physical therapy program started in the second day after injection for 1 hour /three times per week for successive six months.

Group III: The children in this group were treated with Botox A (Allergan, USA) injection of bilateral calf muscles as given to the children in group II. After the injection, the parents were instructed to use rigid AFOs for 23 hours per day for two successive weeks. After that, the parents instructed to wear their children medical shoes. The parents were instructed to perform stretch exercises of the calf muscles five times a week and to walk on heels at least 50 steps a day **[18].**The instructions were also given in written form with follow up to ensure that the children performed the home program.

Statistical Analysis:-

Descriptive statistics were done in the form of mean and standard deviation to summarize gait parameters and PDMS-2. Inferential statistics assessed changes in all measuring variables including: analysis of variance (ANOVA) was used for each measuring variable to compare between the three groups together pre, post (1) and post (2) results. Least significance difference (LSD) was used to show the statistical differences between each two groups post treatment 1 and 2. Repeated measure ANOVA test was used to compare between the pre, post 1 and post 2 results for each group. The level of significance for all statistical tests was set at $p < 0.05$. All statistical analysis was conducted through SPSS (Statistical Package for Social Sciences, version 19).

3. Results

3.1. Subject characteristics

Table 2, presented the mean± standard deviation (SD) of age, weight and height of the three groups. There were non significant differences between the three groups in the mean age, weight and height ($p> 0.05$).

Table 2.Subject characteristics

Variable	group I	group II	group III	t-value	p-value
Age (years)	4.20±0.37	4.40±0.39	4.30±0.33	2.99	0.06
Weight (Kg)	17.10± 1.05	16.77±1.63	16.82±1.23	0.27	0.77
Height (cm)	101.11± 2.20	100.63±1.96	100.85±1.93	0.21	0.81

Data are expressed as mean ± SD Kg-kilograms cm-centimeter P-value- level of significance

3.2. Gait parameters and functional activity

The mean and standard deviation of the gait parameters including (stride length, velocity, cadence) and functional activity were measured.

Results within the groups:

Group (I)**:** The differences were statistically non significant ($P>0.05$) when comparing pre-treatment results to post (1) in all measuring variables. But the changes were statistically significant ($P<0.05$) when comparing post (1) and (2); pre and post (2), as presented in table 3.

Group (II)**:** There were statistically significant differences ($P <0.05$) when comparing pre and post (1); post (1) and (2); pre and post (2) mean values of all measuring variables, as presented in table 4.

Group (III)**:** There were statistically significant differences ($P<0.05$) when comparing pre and post (1) ; pre and post (2) mean values, while statistically non-significant differences were observed ($P>0.05$) when comparing post (1) and post (2) mean values of all measuring variables, as presented in table 5.

Table (3): Gait parameters and PDMS-2 for group I

	Stride length (m)	Velocity (m/sec)	Cadence (steps / min.)	PDMS-2
Pre	0.47±0.02	0.73±0.03	133.93±0.88	2.26±0.05
Post (1)	0.49±0.03	0.74±0.02	133.47±0.99	2.35±0.19
Post (2)	0.64±0.01	0.88±0.01	127.47±0.52	4.83±0.24
p-value (pre / post 1)	-0.02	-0.01	0.47	-0.09
p-value (post 1/ post 2)	-0.15*	-0.14*	6.00*	2.48*

Volume : 4 | Issue : 12 | Dec 2014 | ISSN - 2249-555X

Data are expressed as mean ± SD PDMS-2- Peabody Developmental Motor Scales-version2
P-value- level of significance m-meter min.- minute * -Mean difference is significant at p<0.05

Table (4):Gait parameters and PDMS-2 for group II

	Stride length (m)	Velocity (m/sec)	Cadence (steps / min)	PDMS-2
Pre	0.48±0.04	0.73±0.03	134.07±0.08	2.25±0.05
Post (1)	0.57±0.07	0.84±0.03	127.47±0.52	4.50±0.42
Post (2)	0.73±0.03	0.93±0.02	123.8±0.68	5.60±0.51
p-value (pre / post 1)	-0.09*	-0.01*	6.6*	-2.25*
p-value (post 1/ post 2)	-0.15*	-0.09*	3.67*	-1.10*

Data are expressed as mean ± SD PDMS-2- Peabody Developmental Motor Scales-version2
P-value- level of significance m-meter min.- minute * -Mean difference is significant at p<0.05

Table (5): Gait parameters and PDMS-2 for group III

	Stride length (m)	Velocity (m/sec)	Cadence (steps /min)	PDMS-2
Pre	0.47±0.03	0.74±0.03	134.33±1.05	2.25±0.05
Post 1	0.53±0.05	0.79±0.01	130.53±0.52	4.20±0.41
Post 2	0.53±0.06	0.78±0.04	130.13±0.74	4.40±0.51
p-value (pre / post 1)	-0.06*	-0.04*	3.8*	-1.95*
p-value (post 1/ post 2)	-0.01	-0.01	0.40	-0.2

Data are expressed as mean ± SD PDMS-2- Peabody Developmental Motor Scales-version2
P-value- level of significance m-meter min.- minute * -Mean difference is significant at p<0.05

Results between the groups:
There were non significant differences among the three groups in all measuring variables including gait parameters and PDMS-2 (P >0.05) before starting the treatment which suggested proper sample subdivision. While after 3 and 6 months, the results showed significant differences in all measuring variables among the three groups (P < 0.05).

Comparison of the mean values between each two groups using LSD, presented in table 5 and demonstrated in figures 2, 3 and 4 were as following:

- After three months (post 1): There were significant differences between group I and II groups; between II and III groups in all measuring variables in favor of group II (P<0.05). Also there were significant differences between group I and group III in favor of group III (P < 0.05).
- After six months (post 2): There were significant differences between group I and II groups; between II and III groups in all measuring variables in favor of group II (P<0.05). Also there were significant differences between group I and group III in favor of group I (P<0.05).

Table (6): Comparison of gait parameters and functional activity among the three groups after 3 and 6 months

Parameter	MD post (1)			MD Post (2)		
	group I / II	group II /III	group I/III	group I /II	group II/ III	group I/ III
Stride length (m)	.08*	0.04*	0.04*	0.09*	0.20*	0.11*
Velocity (m/sec)	0.10*	0.05*	0.05*	0.05*	0.15*	0.10*
Cadence (steps /min)	6*	3.06*	2.94*	3.67*	6.33*	2.66*
PDMS-2	2.15*	0.30*	1.85*	0.77*	1.20*	0.43*

Data are expressed as mean ± SD PDMS-2- Peabody Developmental Motor Scales-version2

P-value- level of significance m-meter min.- minute *

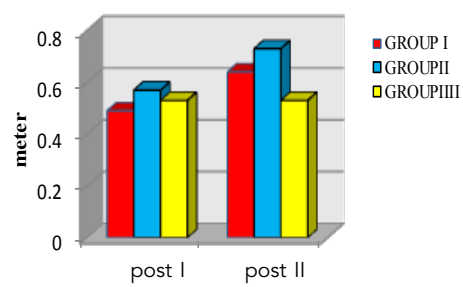

Figure Post 3and 6 months mean values of

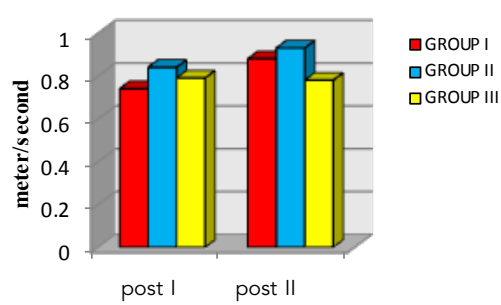

Figure 3. Post Post 3 and 6 months mean values of

Volume : 4 | Issue : 12 | Dec 2014 | ISSN - 2249-555X

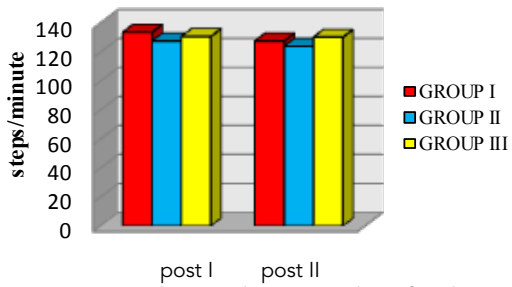

Figure 4. Post 3 and 6 months mean valuesof cadence for the three groups

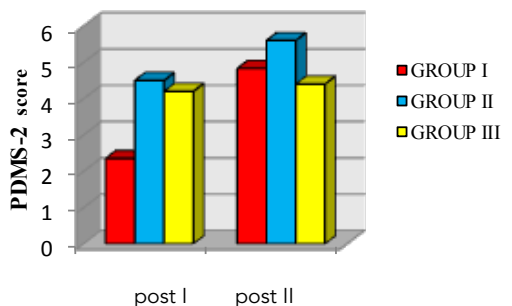

Figure Post 3 and 6 months mean values of Peabody Developmental Motor Scales for the three groups

4. Discussion

Toe walking is a condition that impairs the most common activity of daily living and ambulation Altered gait pattern with excessive plantar flexion is the chief complaint in children with ITW that may provide a partial explanation for postural problems that are common in these children.

Idiopathic toe walking is the persistent toe walking in a normal child in the absence of developmental, neurological, or neuromuscular conditions. It is not a common referral to the general pediatric orthopedic clinics. It is principally a diagnosis of exclusion **[20].**The long-term effect that ITW has on the foot and ankle has not been definitively established, although it has been noted that there is some evidence of excessive external tibial rotation present in long-term toe walkers and a positive association with equines **[21]**.

This study was done to compare between the effects of Botox injection and a designed physical therapy program on gait parameters and functional activity of children with The selected children They were assigned randomly into three groups of equal number. Group I received a designed physical therapy program, group II received Botox injection of bilateral calf muscles and the same physiotherapy program given to group I while group III received Botox injection of bilateral calf muscles only.

The results after three months revealed significant improvement in the group II and III when comparing their pre and post treatment mean values of all measuring variables. Also, significant differences were recorded between group II and III in favor of group II when comparing their post treatment mean values. While non significant improvement were observed in group I. after six months, significant improvement was observed in the group I and II when comparing their post (1) and (2) mean values. Also,significant differences were recorded between group I and IIin favor of group II when comparing their post treatment mean values. While non significant improvement was observed in group III.

The significant improvement which was observed in the group III after three months could be due to the effect of Botox injection. This comes in agreement with **Graham et al. [22] who** stated that, The effect of Botox is a reversible blockage of cholinergic vesicles, thus, causing a flaccid paralysis of the muscle. While the non significant improvement which was observed in the same group after six months could be due to the short term effect of Botox injection. This is confirmed by the findings of **Galli et al.[23]** who reported that, the Botox injections to the gastrocnemius-soleus complex have proven to be an effective short term method by blocking the acetylcholine receptors to disrupt the neuromuscular junction. Botox alone lasts three to four months and is effective for short terms in tone management. **Ibrahim et al.[24]** reported that, the duration of the Botox affects the various variables was interesting. It is well-known that the effects of Botox on the reduction in muscle tone do not persist longer than 3 months because the blocked nerve terminals are recovered by collateral sprouting or regeneration.

The results also supported by the findings of **Stawek and Kilmont[25]** who reported that, patients treated with Botox demonstrated overall functional benefits, such as gross motor function measure (GMFM), despite the increased muscle tone 3 months after Botox -A injection.

The non-significant improvement observed in groupI after three months of treatment comes in agreement with **Oetgen and Peden [26]** who stated that, it is recognized that stretching and physical therapy offer a limited chance of success for ITW, and it is more often used in an attempt to maintain ROM gained by other methods. The long-term results of treatment forITW is unclear as most studies mix a variety of management methods, making it difficult to critically evaluate individual treatment options.

In a long-term study of 14 children with ITW treated with a stretching regimen with or without casting, only 3 children required additional treatment for persistent toe walking after several years [27].

The significant improvement which was observed in the group I after six months due to the effect of a designed physical therapy program comes in agreement with Undequam and Willis[28] who stated that,treatment was 50-70 minutes in length and included stretching, manual therapy and active therapeutic exercise assisted dorsiflexion and strengthening to the lower extremities.

While the significant improvement observed in groupII could be due to the combined effect of Botox injection and a designed physical therapy program.This results could be explained by **Love et al [29]** who stated that, improvement obtained from Botox with physical therapy program could be attributed to children's abundant nervous system plasticity, which accommodates their muscles learning new functions, biomechanical transformation and muscles lengthening acquired by muscle stretching after injection, and the strengthening of antagonist during the period of weakness of the injected muscle.

Conclusion

This study was done to compare between the effects of Botox injection and a designed physical therapy program

Volume : 4 | Issue : 12 | Dec 2014 | ISSN - 2249-555X

on gait parameters and functional activity of children with idiopathic tip-toe walking . Their age ranged from 3 to 5 years. Botox injection of the calf muscle together with a designed physical therapy program is an excellent decision for correcting idiopathic tip-toe walking in children and is more effective than physical therapy program or Botox injection alone. Both physiotherapy and Botox alone could improve gait parameters and functional activity but Physical therapy may need longtime and Botox injection alone has limited and short time effect.

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