Faculty Of physical Therapy
Cairo University

Cairo University

The use of electric stimulation in treating clubfoot in newborn infants

[1]Aliaa R. Youssef, [2] Abdelhalim Nada, [3]Manal Ismail, [4] Amr Azzam

[1] Lecturer of Orthopedic Physical therapy, Cairo University, Egypt.
[2] Senior Physical Therapist, National Institute for Neuro-Motor System, Giza, Egypt
[3] Professor of Orthopedic Physical therapy, Cairo University, Egypt
[4] Consultant of Orthopedic surgery, National Institute for Neuro-Motor System, Giza, Egypt

ABSTRACT

Objective: To investigate the effects of Neuromuscular Electrical Stimulation (NMES) combined with Ponseti method in correcting idiopathic clubfoot.**Methods:** Twenty-eight infants (39 feet), with age ranged from one week to 10 weeks were randomly assigned into two groups: Standard Ponseti group (n=21 feet) received the standard manipulation and casting, and Ponseti plus NMES group (n= 18 feet) received Ponseti method with neuromuscular electrical stimulation. Assessment at baseline and end of treatment (four weeks) included Pirani score, Ankle Dorsiflexion (DF) range, Foot Length (FL), and Calf Circumference (CC).**Results:** Comparing infants before and after treatment showed significant improvement in all measured variables in the two study groups ($P<0.001$). However, with the numbers available, no significant difference could be detected between groups ($P>0.05$).**Conclusions:** Based on our results, combining neuromuscular electric stimulation with standard Ponseti method has no additional therapeutic value during the correction of clubfoot.

Keywords:*Clubfoot; electric stimulation; Ponseti; New born*

INTRODUCTION

Clubfoot is the most common congenital foot and ankle deformity. The estimated incidence of clubfoot ranges from 1 to1.5, in 1,000 live birth, with bilateral involvement occurring in more than 50% of cases [1, 2, 3]. The exact cause of idiopathic clubfoot remains unclear, but current evidence suggests that genetic and environmental factors may play an important role [4, 5]. Clubfoot deformity is characterized by an equinus of the hind foot, adductus and varus of the midfoot as well as a high arch. The Ponseti method is one of the most commonly used and recognized conservative interventions. It is a simple and effective treatment that is based on weekly manipulation and serial casting for 3 to 5 weeks, until the foot is abducted and externally rotated. Then, a percutaneous achilles tenotomy is done followed by casting for approximately 3 weeks. Once correction is achieved, the feet are braced in order to maintain the corrected position and to prevent recurrence [6, 7, 8, 9].

During Ponseti casting period, the baby is not actively using his foot. It is believed that active movement and the use of the limb muscles is essential for growth and development. With the cast worn day and night, it might not be possible to move the limb actively [10].However, muscles can still be stimulated to contract via thecutaneous application of electrical stimulation [11, 12].

Neuromuscular electrical stimulation (NMES) is the electrical stimulation of skeletal muscle through motor or sensory nerves. Stimulation is applied at an intensity sufficient to elicit muscle contraction. The use of NMES as a dynamic intervention to prevent relapses of corrected clubfoot was investigated during the bracing phase of clubfoot. Children receiving NMES showed improvement in ankle ROM, Calf circumference, and Pirani scores with no relapses in any feet during the study period denoting successful outcome. This suggested that electric stimulation is a feasible adjunct treatment to increase ankle ROM and muscles activities during thebracing phase of Ponseti method [10]. Furthermore, NMES applied to ambulant infants values [13].In the previous two studies, children were already ambulant, and adaptive and structural changes

might have occurred. Therefore, the purpose of the study was to investigate the effects of NMES combined with Ponseti method on the correction of idiopathic clubfoot in newly born infants with idiopathic clubfoot.

METHODS

This study was conducted between September 2012 and September 2013. The study was approved the Ethics committee of the Faculty of Physical Therapy, Cairo University Ethics Committee.

Twenty-eight girls and boys (39 clubfeet) with idiopathic clubfoot were enrolled in this study.Participants were eligible to participate in this study if they had a mild to moderate clubfoot scored between 3 and 5 on Pirani Score, and were younger than three months. Patients were excluded if they had any systemic illness or any other associated congenital anomalies, neuro-musculoskeletal diseases, or underwent unsuccessful treatment for clubfoot.

Based on the above-mentioned criteria, the Ponseti plus NMES group consisted of 18 feet (10 unilateral and 4 bilateral; 8 boys and 6 girls). The Ponseti group consisted of 21 feet (7 unilateral and 7 bilateral; 10 boys and 4 girls).

Initial screening was done to assess the eligibility of infants to participate in the study. Then, researchers gave full verbal explanation of the purpose and procedure of the study and the parent or guardian was asked to sign an informed consent. For each participant, first, routine demographic data and relevant medical history were taken. Assessment at baseline and following the treatment period included clubfoot severity as indicated by the Pirani score. This is a 6-point scoring system that evaluates the severity of the posterior crease, emptiness of the heel, rigidity of the equinus, curvature of the lateral border of the foot, severity of the medial crease and position of the lateral part of the head of the talus. Each of these clinical signs can be scored as zero indicating no abnormality; (0.5) reflecting a moderate abnormality and (1) indicating severe abnormality. Thus, a normal foot would score (0), while a severely deformed foot would score (6). This scoring system is quick and easy to apply at clinical settings. It has an excellent interobserver reliability (0.9) and can predict the number of casting needed for clubfoot correction (r= 0.72) [14, 15, 16, 17].

In this study, the Piriani score was done by a trained orthopedic resident, who was blinded to patients' grouping, whereas the remaining measures were done by a trained physiotherapist who was blinded to patient's grouping as well.

Ankle dorsiflexion (DF) range was also measured using a universal baseline handheld goniometer (NexGen Ergonomics Inc., Quebec, Canada) with the infant in a supine lying position and the knee flexed. DF range is an objective measurement for clubfoot assessment that is valid and reliable (r=0.89-0.97). (18,19)Ankle dorsiflexion was measured to assess the degree of clubfoot correction. A complete correction is considered when ankle DF range is 10 to 15 degrees. The use of goniometer to assess ranges in children has been proved valid and reliable, however, an error of approximately 5-7 degrees has been reported [25].

Also, foot length (FL) was measured between the furthest points of toes and heel using foot print on a blank paper. Again this is a valid and reliable (r=0.98) anthropometric assessment[19] that correlates well with patients satisfaction of treatment [18]. Finally, calf circumference (CC) was measured using a tape at the widest point of the calf muscles while the infant was in a relaxed supine lying position and the knee flexed. This is a reliable objective method (r=0.93-0.99)(18,19) that indirectly reflects strength of this muscle group and that correlates with function and pain perceived in patients with clubfeet [18]. Each assessment was done by an assessor who was blinded to infants' grouping. Testes were repeated three times and the mean was calculated and used for further statistical analyses.

Patients' feet were randomly allocated by sealed envelopes into two groups, this means that one patient with bilateral clubfeet could have each foot allocated to a different group. The first group was the standard Ponseti (n=21) that underwent manipulation and casting using standard procedure, and the second group was Ponseti combined with NMES (n=18) that received electrical stimulation through a window opened in the cast (Fig.1). First, the physiotherapist placed the electrodes as it is shown in (Fig.2). Then, physiotherapist turned on the NMES stimulator (EMS 7500; TX USA, 78704) and gradually increased the intensity until a slight eversion of foot was observed or a flicker contraction was palpated. Each time a new cast was applied, a window was opened and kept covered with adhesive tapes.

The parameters of NMES were as follows: ON: OFF cycle of 20:20s, with a 5s ramp, a frequency of 25Hz, pulse width 300µs. The stimulation intensity was set where visible movement of foot was achieved and was adjusted weekly and the treatment duration was set at 15 minutes [20].

Every week, the infant received three sessions; the first one was given beforemanipulation and casting. In the next two sessions, stimulation was done through the window while the cast was on. Before the application of the electrical stimulation, physiotherapist cleaned the skin

using alcohol swaps, and then placed the electrodes as described earlier in order to obtain ankle foot eversion. The threshold intensity was recorded for every infant in intervention group. Infant needed to be in relaxed position during stimulation.

Fig.1: The application of neuromuscular electric stimulation through a window opened in the cast.

Fig.2: Electrodes placement for evertor muscle stimulation

The main outcome measures included Pirani score, FL, CC, and DF range at baseline and at the end of the casting and before tenotomy. Data are presented as means ± SD. All statistical analyses were done using SPSS for windows, version21.0 (SPSS, Inc., Chicago, IL). Un-paired and paired t-test were done to detect between and within group differences with regards to CC, FL and DF. For Pirani scores, between groups comparisons were done using the Mann-Whitney test and within group comparisons were done using the sign rank test. In addition, Chi- square was done to compare the two groups with regards to sex distribution and lateralism. For all statistical analyses, the p-value was set at $P<0.05$ to declare significance.

RESULTS

Initially, 43 feet in 32 infants were evaluated. Three of the eligible infantswere then excluded (drop out =9.3%). One patientwith bilateral clubfeet was diagnosed with meningocele, the second infant completed his treatment using the French Physiotherapy method. The third infant's parents requested to withdraw from the study and to have their child treated with the standard method. Thus, this study was completed on 39 feet from 28 participants completed this study. The Ponseti plus NMES group consisted of 18 feet (10 unilateral and 4 bilateral; 8 boys and 6 girls) with a mean age of 5.7 (± 3.9) weeks. The Ponseti group consisted of 21 feet (7 unilateral and 7 bilateral; 10 boys and 4 girls) with a mean age of 5.6 (± 3.8) weeks. The followup period for the Ponseti group ranged from 3-7; with a mode of 4 weeks. For the Ponseti plus NMES, followup ranged from 4 to 7; with a mode of 4 weeks. Since both group had a viable casting period, and to avoid the effect of normal development and growth on results, only data from week 4 (the most frequent duration) were analyzed to reflect post-treatment effects. There were no significant differences between two groups with regard to the age and gender ($P>0.05$). However, the Ponseti group had a higher number of bilateral clubfeet than that of the Ponseti with NMES group ($P=0.04$).

With the numbers available, no significant difference could be detected between groups ($P>0.05$). However, all measured variable showed significant within group differences ($p<0.0001$) as shown in table 1.

DISCUSSION:

The main outcome measures for this study were clubfoot severity as indicated by the Pirani score and ankle DF range as well as foot development rate as indicated by CC and FL. These measures are valuable assessment tools in clinical decision- making with regards to clubfoot management [18]. To authors' knowledge, this is the first study to use NMES with clubfoot in infants before the age of walking.

In this study, it was hypothesized that NMES plus Ponseti method wouldimprove the correction of idiopathic clubfoot than that of the standard Ponseti method. With the numbers available, no significant difference between groups could be detected ($p>0.05$) and the hypothesis was rejected. However, the two groups showed significant improvement in all measured variables following treatment compared to baseline measurements. This implies that improvement shown in the two groups could be attributed to the manipulation and casting rather than to the addition of NMES.

Variable			Ponseti + NMES (N= 18 feet)		Ponseti (N=21 feet)	
			Pre	Post	Pre	Post
Pirani score	Median (Range)		4 (3 – 5)	1 (0.5 – 2)	4 (3 – 5)	1.5 (0.5 – 2.5)
	P-value		<0.001		<0.001	
Ankle Dorsiflexion (Degrees)	Mean ± SD		-7.22± 2.55	1.66± 2.97	-7.38± 2.55	0.24±2.48
	P-value (95%CI) (within group)		<0.001 (6.88 – 10.89)		<0.001 (6.07 – 9.16)	
	P-value (95% CI) (between groups)	Pre	0.848 (-1.51 – 1.82)			
		Post	0.111 (-0.34 – 3.19)			
Calf Circumference (cm)	Mean ± SD		10.83 ±2.21	13.30±2.04	10.47±2.29	12.68±2.1
	P-value (95%CI) (within group)		<0.001 (1.98 – 2.95)		<0.001 (1.63 – 2.79)	
	P-value (95% CI) (between groups)	Pre	0.616 (-1.10 – 1.84)			
		Post	0.352 (-0.72 – 1.97)			
Foot Length (cm)	Mean ± SD		7.28± 1.37	8.64±1.68	7.10 ±0.43	8.44 ±0.89
	P-value (95%CI) (within group)		<0.001 (1.12 – 1.61)		<0.001 (1.05 – 1.64)	
	P-value (95% CI)(between groups)	Pre	0.567 (-0.46 – 0.83)			
		Post	0.645 (-0.66 – 1.06)			

Table 1: Pre- and Post-treatment values for Pirani score, Ankle Dorsiflexion range (DF), Calf Circumference (CC) and Foot Length (FL) for the Posneti and Posnei plus NMES groups. Data are shown as Median (range) for the Piraniscore and as means (±SD) for all remaining variables

To declare significance P-value <0.05 (*) indicates significant difference.

For all measured variables, no significant differences were found between the two groups at baseline indicating homogenous groups ($p>0.05$). With the numbers available, no significant difference could also be detected between groups following treatment by 4 weeks ($p>0.05$).

For Pirani score, the severity of deformity at initial assessment was moderate in the two groups (mean=3.9). This severity significantly improved to mild following the treatment in the two study groups (mean=1.3, $p<0.05$). The magnitude of improvement in Pirani score shown in this study is consistent with that reported by Abbas et al. [21] and Changulani et al. [22].

In this study, the mean ankle DF range significantly increased in the two groups to reach 5 to 10 degrees. This implies incomplete foot correction in both groups. Full correction in clubfeet with moderate severity is expected to occur within 3 to 5weeks (for healing after tenotomy and complete ankle DF range) [16].Ankledorsiflexion range has been reported to gradually improve with serial casting used in the classical Ponseti method that indicates improvement in ankle motion and reduction of bone mal alignment within the deformed feet [23]. When El-Hawary et al. [24] compared between cast treatment and Physical therapy method for clubfoot correction, increased ankle DF range was seen in 48% in the Ponseti group and 12% in patients receiving Physical Therapy. It should also be emphasized that in the current study, a universal handheld goniometer was used which may have given rise to an error up to 7 degrees as stated earlier in the methods section.

Calf Circumference was measured using a measuring tape. This is a simple, valid and reliable clinical method. However, an error of (5%) may exist [19].Although many confounding factors may affect CC such as disuse, malnutrition, and neurogenic atrophy, yet the patients recruited in this study were healthy from any physical or organic dysfunction other than the clubfoot. This means our sample was homogenous and was not expected to have any systemic cause of atrophy other than that associated with clubfoot. Another limitation of this method is its inability to distinguish between changes in muscle size as a result of fat or lean mass changes. However, our baseline statistical analysis showed no significant difference between groups indicating comparable groups with regards to CC. Following treatment, children in the two groups showed significant improvement in CC. Thus, it could be safely assumed that changes seen following the treatment are the result of normal growth and manipulative correction that could have placed the muscle in a better alignment for function. These effects are expected to besimilar in both groups. The lack of significant differences between the classical Ponseti technique and Ponseti with NMES are consistent with the findings of Gelfer et al. [10]. Although, their study was done on older children who had a relapsed clubfeet treated with abduction brace, which means the children in their study had more challenging foot deformities.

FL was measured using a measuring tape from footprints collected on blank papers. Increase of FL is an indicator of correction of mid foot. There is an inverse relation between FL measurements and objective score grading (Pirani score

and angles of the foot) [18]. Thus an increase in FL means a decrease of lateral curvature and medial crease of foot; which lead to a decrease in Pirani severity score. With a more severe deformity, structures on medial and posterior aspect of the foot are tight. Manipulation and stretching techniques that applied by Ponseti were reported to be the best was to correct these structures [23].

In our study, infants in the two groups showed significant increase in foot length, which could be attributed to the ponseti technique itself as well as normal growth. Improvement of FL shown in this study was consistent with those findings found by Abbas et al. [21] who reported a significant increase in FL between pre and post correction.

It should be emphasized that this study is the first to report the effect of NMES on newly born children before the age of walking. This age was selected to ensure freedom from secondary musculoskeletal adaptive changes and to target the deformity early, to allow normal muscle activity that is essential for normal growth and development. Literatures search revealed only two studies that investigated the effect of combining NMES with Ponseti method. One study was conducted on children withrelapsed clubfoot [10]. The second study was conducted in children aged between 2.5and 3.5 years old and who never had their clubfoot previously treated [13]. The later study reported only changes in foot pressure, and no data were given considering changes in clubfoot severity, ankle range of motion, foot length or calf circumference. Both studies applied NMES for 30 minutes daily. In the current study, NMES was applied for 15 minutes, every other day. This duration was selected based on clinical experience and matched the shortest duration reported in literatures. This duration seemed well tolerated by those infants as evident by their response and the extent of skin hyperemia seen after the initial testing session. The duration of electric stimulation varies widely among different studies and lack standardization,[26, 27, 28] with no studies reported for age similar to that enrolled in the current study.

The current study has a few limitations such as the small sample size, larger sample size is recommended. Also, data were analyzed four weeks following casting; which is a relatively shortfollowupperiod. However, this study aimed at targeting infants during the casting phase of Poseti method and before carrying out tenotomy or applying abduction brace. Also, this study compared pre-post changes within the treated side. The contra lateral side was not used as an internal control due to bilateral involvement of many cases. An internal control would help judging whether the anthropometric variables considered in this study (FL, CC, DF) have returned to normal values or not. Finally, Measurements were done using simple clinical methods, yet, they have some inherited errors. A more accurate and sensitive methods are recommended in order to detect subtle changes. These may include electromyography and dynamometers (to assess muscle strength), electrogoniometer or motion tracking systems (to detect ankle range of motion) and ultrasonography (to detect muscle thickness).

CONCLUSION

Based in our results, there was no statistical evidence that adding NMES had any additional therapeutic value to the standard Ponseti method.

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الملخص العربي

مقدمه: يتم تصحيح القدم الحنفاء ذاتيا عادة باستخدام طريقة بونستى او طريقة العلاج الطبيعى الفرنسيه. طريقة بونستى هى الاوسع استخداماً بالرغم من حرمان الطفل مؤقتا من الحركه الطبيعيه بسبب الجبس. لذلك هذه الدراسه تهدف لتحسين نتائج طريقه بونستى عن طريق اضافة التنبيه العصبى العضلى الكهربائى. **الغرض:** اختبار مدى فاعليه التنبيه العصبى العضلى الكهربائى مع طريقة بونستى لتصحيح القدم الحنفاء**طريقة البحث:**٢٩ طفل (٣٩ قدم) اعمارهم من اسبوع الى 10اسابيع، تم تقسيمهم عشوائيا الى مجموعتين: المجموعه الاولى: طريقة بونستى مع التنبيه العصبى العضلى الكهربائى (18قدم) و المجموعه الثانيه: تتلقى طريقه بونستى (21قدم). تم متابعة كلا المجموعتين حتي اتمام الاصلاح او الاحتياح الي عمليه اطاله اوتار. تم تقييم الأطفال

في بدايه و نهايه فترة العلاج باستخدام مقياس بريانى – محيط الساق- طول القدم ومقياس حركه الكاحل. **النتائج:** اظهرت المقارنه بين المجموعتين قبل و بعد العلاج تحسن كبير مع وجود فروق احصائيه ذات دلاله فى محيط الساق و مقياس بريانى طول القدم و حركه الكاحل. لم توجد فروق احصائيه ذات دلاله عند مقارنه كلتا المجموعتين معا.

الخلاصه و التوصيات: بناء على النتائج لا يوجد دليل احصائى على ان اضافه التنبيه العصبى العضلى الكهربائى له فائده علاجيه لطريقة بونستى. و ان طريقة بونستى مع او بدونالتنبيه العصبى العضلى الكهربائى قادره علي تصحيح القدم الحنفاء.

الكلمات الدالة: (طريقه بونستى ، القدم الحنفاء ذاتيا، التنبيه العصبي العضلى الكهربائي).