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ORIGINAL RESEARCH ARTICLE

Effect of Extracorporeal Shock Wave Therapy on Gait Pattern in Hemiplegic Cerebral Palsy

A Randomized Controlled Trial

ABSTRACT

El-Shamy SM, Eid MA, El-Banna MF: Effect of extracorporeal shock wave therapy on gait pattern in hemiplegic cerebral palsy: a randomized controlled trial. *Am J Phys Med Rehabil* 2014;93:1065–1072.

Objective: The aim of this study was to investigate the effects of shock wave therapy on gait pattern in children with hemiplegic cerebral palsy.

Design: Fifteen children were assigned to the study group, whose members received shock wave therapy (1500 shots/muscle, frequency of 5Hz, energy of 0.030 mJ/mm², one session/wk). Another 15 were assigned to the control group, whose members participated in a conventional physical therapy exercise program for 3 successive months. Baseline and posttreatment assessments were performed using the Modified Ashworth Scale to evaluate spasticity degrees and using a three-dimensional gait analysis to evaluate gait parameters.

Results: Children in the study group showed a significant improvement when compared with those in the control group ($P < 0.005$). The Modified Ashworth scores after treatment were 1.86 (0.22) and 1.63 (0.23) for the control and study groups, respectively. The gait parameters (stride length, cadence, speed, cycle time, and stance phase percentage) after treatment were 0.5 m, 125 steps/min, 0.6 m/sec, 0.48 sec, and 50.4% and 0.74 m, 119 steps/min, 0.75 m/sec, 0.65 sec, and 55.9% for the control group and the study group, respectively.

Conclusions: Shock wave therapy may be a useful tool for improving spasticity and gait pattern in children with hemiplegic cerebral palsy.

Key Words: Extracorporeal Shock Wave Therapy, Cerebral Palsy, Hemiplegia, Gait

Cerebral palsy (CP) is one of the leading causes of movement and posture disorders, which occurs in 2–3 of every 1000 individuals, and the cost of care is estimated to be 8 billion dollars. Many children with CP have a severe disability, such as the inability to walk. Improving the ability to walk is often the essential therapeutic goal for such children.¹

These neuromusculoskeletal disorders affect upright stance, balance, and the ability to walk. As a consequence, gait performance in these children is poor when compared with that of healthy children, leading to difficulties in carrying out daily and even leisure activities.²

Children with CP have many neurologic deficits that interfere with motor function and daily activities. Because of the magnitude of the pathology, walking velocity decreases, and energy cost per time and energy cost per distance increase. The children with hemiplegic type are the most ambulatory group. However, they generally have dynamic equines on the affected side throughout the gait cycle.³

Children with hemiplegic CP had a longer gait cycle, slower walking speed, and longer support phase than did healthy children. The support phase was longer than the swing phase in children with hemiplegic CP. There were significant differences in the angles of the hip, knee, and ankle joint between children with hemiplegic CP and healthy children at the moment of touching the ground and buffering and during pedal extension. Children with hemiplegic CP had poor motor coordination during walking, which resulted in a short stride, high stride frequency to maintain speed, more obvious swing, and poor stability.^{4,5}

Extracorporeal shock wave therapy (ESWT), defined as a sequence of single sonic pulses characterized by high peak pressure (100 MPa), fast pressure rise (<10 ns), and short duration (10 μ s), is conveyed by an appropriate generator to a specific target area with an energy density in the range of 0.003–0.890 mJ/mm². Recent studies have indicated that ESWT is effective for treatment of musculoskeletal diseases such as pseudoarthrosis, calcific tendinitis of the shoulder, epicondylitis, plantar fasciitis, and several inflammatory tendon diseases.^{6–8}

A few articles have assessed the efficacy of ESWT in CP. SWT seems to be safe, noninvasive, not painful, and without complications. These preliminary findings suggest that SWT may be useful in decreasing flexor tone in the lower limb spasticity in children with CP. This therapy could open a new field of research into the noninvasive treatment of children with CP.⁹

The aim of this study was to determine the effects of ESWT on gait pattern in children with hemiplegic CP.

MATERIALS AND METHODS

Subjects

Thirty children with hemiplegic CP, with ages ranging from 6 to 8 yrs, participated in this study after their parents signed consent forms for their children's participation. To avoid a type II error, a preliminary power analysis (power, 0.87; α = 0.05; effect size, 0.5) determined a sample size of 30 for this study. They were selected from the outpatient clinic of the Faculty of Physical Therapy, Cairo University. The children were enrolled in this study if they met the following criteria: (1) CP diagnosed by both a pediatric neurologic physician and a physical therapist, (2) no previous surgery interventions in the area of the ankle, (3) no drug being taken for spasticity control, (4) no previous treatment with botulinum toxin at least 7 mos before the procedure with ESWT, (5) good vision, (6) ability to comprehend instructions, and (7) ability to walk without the use of walking aids. The study was approved by the ethical committee of the Faculty of Physical Therapy, Cairo University.

Randomization

For this study, 35 children were identified as potential participants. Three children were excluded because they failed to fulfill the inclusion criteria, and two children's parents refused to participate in the study. Randomization was performed using sealed envelopes. The investigator prepared the sealed envelopes, which contained a piece of paper indicating whether each participant was in the experimental group (SWT) or the control group (conventional physical therapy program). Allocation occurred before the initial assessment. The experimental design is shown as a flow diagram in Figure 1.

Procedures

Each child was evaluated for the spasticity degrees and gait parameters before the treatment (pretreatment) and at the end of 3 mos of treatment (posttreatment) by the same examiner who was blinded regarding the group to which each child was assigned.

The degree of ankle plantarflexor spasticity was evaluated using the Modified Ashworth Scale (MAS). The child was in a supine position, with the lower limb in extension, the head in midline, and the arms alongside the trunk. The therapist, on the side being

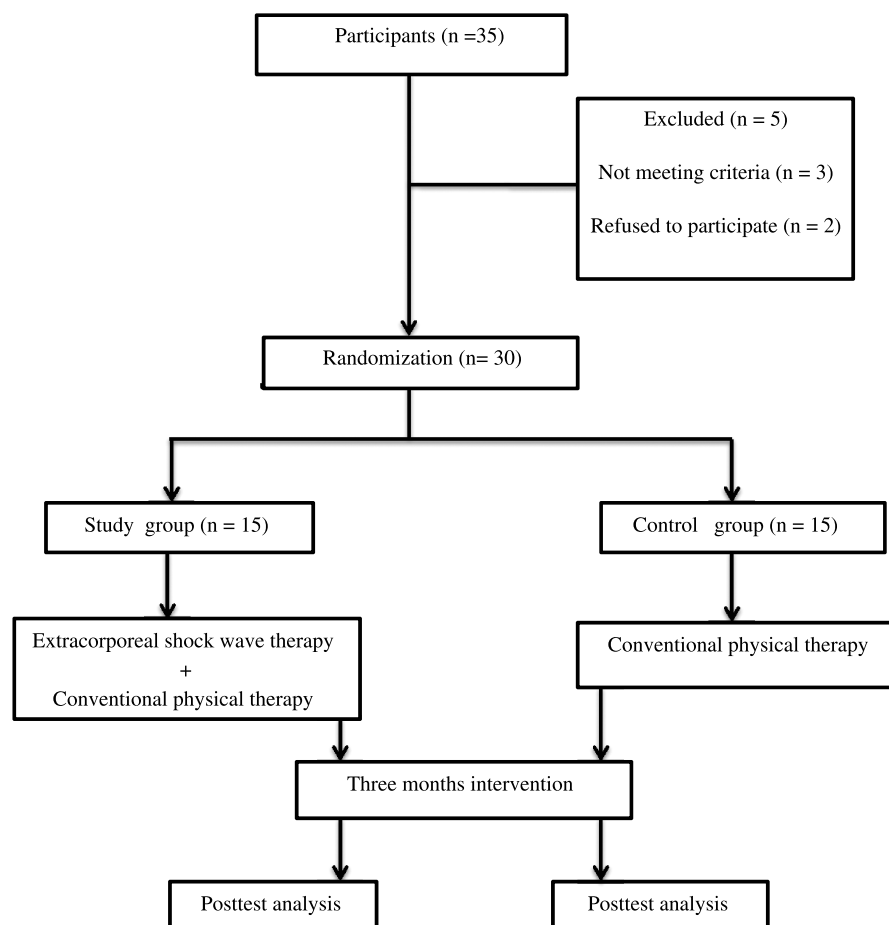


FIGURE 1 Flow diagram showing the children participating in the study.

tested, placed one hand under the ball of the foot, whereas the other hand stabilized the limb around the ankle joint. The therapist then moved the ankle into maximum possible dorsiflexion. After performing three test movements, the therapist graded the resistance felt with a single score, based on the MAS. The MAS grades spasticity according to six ordinal levels, from 0 “normal muscle tone” to 4 “affected part(s) rigid in flexion or extension.”¹⁰

Gait analysis was evaluated using the three-dimensional gait analysis and was recorded at 120 Hz using a six-camera motion capture system (Qualisys; Qualisys Inc, Goeteborg, Sweden). Before data collection, the motion capture system was calibrated when the mean residual for each camera was only less than 1.6 mm according to the guidelines. The accuracy of the three-dimensional gait analysis was estimated to be 1.5–3.0 mm. Retroreflective markers (diameter, 14 mm) were attached to specific anatomic landmarks including the anterior superior iliac spine, the superior border of the patella, a lateral point to the knee joint line, the tibial tuberosity, the lateral malleolus, the posterior aspect of the heel on the calcaneus bone, and between the second and third

metatarsal heads of the foot. The participants stood comfortably with their feet placed shoulder-width apart on the floor, equidistant from the midline, and were recorded. The parents confirmed that the performance was representative of their children’s common gait pattern. Movements were recorded simultaneously with each camera and stored on a computer disk for analysis. Motion and calculations were recorded using the Q-trace C version 2.51, Q-trace V version 2.60, and Q-Gait 2.0 software (Qualisys; Qualisys Inc, Gothenburg, Sweden) for each time frame, along with joint angles and temporal parameters. For each child, three walking trials were recorded, with at least two acceptable trials. Stride length, gait speed, cadence, cycle time, and stance phase percentage were compared with age norms.³

Treatment

The participants were allocated to either the study group (SWT) or the control group (conventional physical therapy program). Both treatment groups received conventional physical therapy program, which included neurodevelopmental techniques,

TABLE 1 General characteristics of both the control and study groups

Item		Control		Study	
		Frequency	%	Frequency	%
Sex	Males	9	60	9	60
	Females	6	40	6	40
Affected side	Right	8	53.33	10	66.67
	Left	7	46.67	5	33.33
Age, mean (SD), yrs		6.8 (0.7)		6.93 (0.8)	
SD, standard deviation.					

muscle stretching, strengthening exercises, proprioceptive training, and balance and gait training, for three mos (1 hr/day, 3 days/wk).

Shock Wave Instrumentation and Treatment

An electromagnetic coil lithotripter (Modulith SLK; Storz Medical AG, Tagerwillen, Switzerland) provided with in-line ultrasound, radiographic, and computerized aiming (Lithotrack system; Storz Medical AG) was used. The pressure pulses were focused on the hypertonic muscles of the lower limb; 1500 shots were used to treat each gastrocnemius muscles and soleus muscles mainly in the middle of the belly using an ultrasound pointer guide. The energy applied was 0.030 mJ/mm². The frequency that was used was 5 Hz, with a pressure of 1.5 bars, burst mode, one session/wk for 3 mos. The therapy is painless and does not require any kind of anesthesia or the use of analgesic drugs.¹¹

Data Analysis

Data were analyzed using the SPSS version 16.0 (SPSS, Chicago, IL). Descriptive statistics of mean and standard deviation presented the children's ages, MAS scores, and gait parameters. Differences between and within groups of the pretreatment and posttreatment values were assessed using Student's *t* test. A *P* < 0.05 was accepted as significant.

RESULTS

Thirty children (18 boys and 12 girls) with hemiplegic CP were included in this study. Participants were randomized to the control and study groups. There was a mean (SD) age of 6.8 (0.77) yrs and 6.93 (0.8) yrs for the control and study groups, respectively. The demographic and clinical characteristics of the participants in both groups are listed in Table 1. These data indicated that the groups had similar demographic characteristics.

Before treatment, there were no statistically significant differences (*P* = 0.73) in the mean values of MSA scores between the control and study groups,

as presented in Table 2. In contrast, there was a statistically significant difference (*P* = 0.009) between the mean values of MAS scores obtained during the baseline and posttreatment assessments. The MAS scores' posttreatment mean (SD) values were 1.86 (0.22) and 1.63 (0.23) for both the control and study groups, respectively. These results indicated that the children in the study group showed remarkable improvement in spasticity when compared with the children in the control group.

Before treatment, there were no statistically significant differences in the mean values of gait parameters (stride length, cadence, speed, cycle time, stance phase, and swing phase percentage) between the control and study groups (*P* > 0.05), as presented in Table 3. In contrast, there was a statistically significant difference between the mean values of gait parameters obtained during the baseline and posttreatment assessments (*P* < 0.05). These results indicated that the children in the study group showed remarkable improvement when compared with the children in the control group, as presented in Table 4.

The mean (SD) values of stride length for the control and study groups were 0.5 (0.07) and 0.74 (0.09) m, respectively. The percentage of improvement was 48% in favor of the study group. The mean (SD) values of cadence after treatment for the control and study groups were 125 (4.23) and 119.93

TABLE 2 Pretreatment and posttreatment mean values of Modified Ashworth Scale scores within each group and between groups

Item	Pretreatment, X (SD)	Posttreatment, X (SD)	<i>P</i>
Control group	2.27 (0.56)	1.86 (0.22)	0.017
Study group	2.34 (0.48)	1.63 (0.23)	0.001
<i>P</i>	0.73	0.009	

SD, standard deviation; X, mean.

TABLE 3 Comparison of the mean values of gait parameters before treatment for both the control and study groups

Gait Parameters	Stride Length, m		Cadence, steps/min		Speed, m/sec		Cycle Time, sec		Stance Phase, %		Swing Phase, %	
	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study
X	0.38	0.4	130	131.3	0.47	0.47	0.37	0.4	45.33	46.53	54.67	53.47
SD	0.08	0.08	3.96	4.75	0.08	0.07	0.07	0.08	1.8	1.68	1.8	1.68
MD	-0.02		-1.33		-0.003		-0.027		-1.2		1.2	
T	0.68		0.84		0.24		1		1.88		1.88	
P	0.50		0.41		0.81		0.32		0.07		0.07	
Significance	NS		NS		NS		NS		NS		NS	

MD, mean difference; NS, not significant; SD, standard deviation; T, paired t value; X, mean.

(5.11) steps/min, respectively. The percentage of improvement was 4.06% in favor of the study group. The mean (SD) values of speed after treatment for the control and study groups were 0.6 (0.07) and 0.75 (0.08) m/sec, respectively. The percentage of improvement was 25.5% in favor of the study group. The mean (SD) values of cycle time after treatment for the control and study groups were 0.48 (0.07) and 0.65 (0.05) secs, respectively. The percentage of improvement was 34.09% in favor of the study group. The mean (SD) values of stance phase percentage after treatment for the control and study groups were 50.47% (1.85%) and 55.93% (1.67%), respectively. The percentage of improvement was 10.82% in favor of the study group. Moreover, the mean (SD) values of swing phase percentage after treatment for the control and study groups were 49.53% (1.85%) and 44.07% (1.67%), respectively. The percentage of improvement was 11.02% in favor of the study group, as presented in Table 4.

DISCUSSION

The results of this study indicated that a 3-mo program of combined SWT and physical therapy produced better improvement in spasticity and gait

pattern compared with a 3-mo program of physical therapy alone (Tables 2, 4).

Significant improvement in both groups in all measuring variables (spasticity and gait parameters) was noted after 3 mos of treatment. However, higher improvement was achieved in the study group in all measuring parameters. The results of this study come in agreement with those of Amelio and Manganotti,⁹ who first studied the benefits of focused shock wave therapy in children with CP and found a long-lasting reduction in muscle tone of the spastic muscles. Their article included 12 children with spastic CP. The protocol consisted of one placebo and one active session 6 wks later (1500 shots were used in each of the gastrocnemius and soleus muscles). The effect of the active treatment lasted 4 wks. In this study, the authors used a similar protocol but applied ESWT, which is less painful, better tolerated, and cheaper in comparison with focused shock wave therapy.

In an earlier study by Manganotti and Amelio,¹² investigating the effect of SWT on muscle spasticity in patients after stroke, they did not find any changes in the F amplitude, which measures spinal excitability. They also did not observe any signs of

TABLE 4 Comparison of the mean values of gait parameters post treatment for both control and study groups

Gait Parameters	Stride Length, m		Cadence, steps/min		Speed, m/sec		Cycle Time, sec		Stance Phase, %		Swing Phase, %	
	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study	Control	Study
X	0.5	0.74	125	119.93	0.6	0.75	0.48	0.65	50.47	55.93	49.53	44.07
SD	0.07	0.09	4.23	5.11	0.07	0.08	0.07	0.05	1.85	1.67	1.85	1.67
MD	0.24		5.07		0.15		0.16		5.46		5.46	
Improvement, %	-48		4.06		-25.5		-34.09		-10.82		11.02	
T	7.48		2.96		5.27		7.13		8.51		8.51	
P	<0.0001		<0.006		<0.0001		<0.0001		<0.0001		<0.0001	
Significance	HS		HS		HS		HS		HS		HS	

HS, highly significant; MD, mean difference; SD, standard deviation; T, paired t value; X, mean.

denervation in the treated muscles, which excludes a direct effect on the peripheral nerves; hence, the effect of SWT could not be explained by neuromuscular block as after the application of botulinum toxin. On a functional level, a decrease in the MAS score has been observed, with a contemporary increase in the range of motion and, for the lower limbs, a significant increase in the plantar surface area and peak pressure at the pedobarometric evaluation.⁹ In vivo studies on healthy rats suggest that ESWT can affect the neuromuscular junctions, causing degeneration and a reduction in the number of acetylcholine receptors, which in turn induces a significant decrease in the maximum compound muscle action potential.¹³

More recently, in a randomized, placebo-controlled clinical trial, the effects of radial ESWT on spasticity consequent of CP were analyzed.¹⁴ The positive results, decrease in the MAS score, and increase in the range of motion were statistically significant compared with the placebo group and were maintained for at least 2 mos after treatment.

Previous studies explained the mechanism of ESWT as the effect of the generation of nitric oxides (NOs),¹⁵ the effect on spinal cord excitability,¹⁶ the effect of mechanical vibration,¹⁶ the effect on the Golgi tendon organ,¹⁷ or the passive stiffness of muscles determined by inactive connective tissues.¹² Considering that the NOs generated by ESWT involve the formation of neuromuscular junctions in the peripheral nervous system and play important roles in neurotransmission, memories, and synaptic plasticity in the central nervous system^{6,13} along with a recent report from an interesting study conducted with rats indicating that spasticity was relieved because neuromuscular transmission was hindered by ESWT in neuromuscular junctions,¹⁸ NOs seem to play core roles in spasticity-relieving mechanisms.¹³

The results of this study come in agreement with those of Gonkova et al.¹¹; they stated that clinical and instrumental data support the effectiveness of ESWT in reducing muscle spasticity in children with CP. The baropodometric findings showed changes in the foot contact area on the affected side and a significant increase in the peak pressure values of the heel, which is an indirect sign of reduced spasticity of the plantar flexors. In particular, the entire plantar surface area increased after ESWT, showing that the gait pattern improved. The initial contact of the foot with the ground changed from toe to heel. This leads to a more normal gait pattern and usually contributes to the improved body stability of the children.

ESWT is known to be effective in musculoskeletal diseases for treating pain, inflammation, or injury to a ligament. It produces mechanical effects such as regeneration of degenerated tissue, neovascularization, and resorption of calcium deposit^{19,20} and also physiologic responses such as changes of epithelial cell permeability, free radical formation, change of cell membrane permeability, NO formation, and variable growth factor formation.^{12,21,22}

NO is involved in neuromuscular junction formation in the peripheral nervous system²³ and in important physiologic functions of the central nervous system, including neurotransmission, memory, and synaptic plasticity.¹⁶ NO synthesis has been suggested as an important mechanism to explain the effectiveness of ESWT in the anti-inflammatory treatment of different tendon diseases.^{15,20,22,24}

A direct effect of shock waves on fibrosis and on the rheologic properties of the chronic hypertonic muscles in CP should be considered together with the documented therapeutic effect on bone and tendon diseases.^{8,25-27}

We might consider possible thixotropy effects of shock waves on tissues and vessels of the treated muscles.^{15,21} The effect of mechanical stimuli of shock waves on the muscle fibers next to the tendon cannot be excluded.¹⁶ Continuous or intermittent tendon pressure can decrease the spinal excitability without long-lasting clinical or neurophysiologic effects.

The results of this study come in agreement with those of Shrivastava and Kailash²⁸; they stated that ESWT has been used in medical practice for the last decades in chronic tendinopathies and also in the treatment of spasticity. There are two basic physical effects of ESWT: a primary effect (which is a result of the direct generation of mechanical forces, concentrated at the treatment point) and a secondary effect (a result of the indirect mechanical forces caused by cavitation).

No previous three-dimensional motion capture analysis study that has investigated the effect of SWT in such children includes longitudinal quantitative and kinematic data regarding changes in gait function associated with motor recovery. The lack of a quantitative and standardized method for gait measurement, based on three-dimensional kinematics and temporal parameters, remains a critical issue in assessing the effects of SWT in children with CP. So, the present study is the first study that conducted a three-dimensional gait analysis to determine the effects of ESWT on gait pattern. Objective and quantitative gait assessments are essential for the evaluation of functional loss or treatment results as well as for the estimation of prognoses.

The clinical assessment, which is frequently used in spasticity studies, is disadvantageous in that the subjectivity of the testers is quite likely to be involved in the evaluation, the reliability of the results is low, and the differences between grades are large; therefore, changes in spasticity cannot be sensitively represented.²⁹

The selection of age group in this study confirms the findings of Sutherland et al.,³⁰ who revealed that, by the age of 7 yrs, the gait pattern, by standards of movement, is fully matured mechanically and physiologically. They stated that the temporal and distance variables continue to vary with age.

The present study has several limitations. The actual effective mechanism of ESWT on spasticity was not determined, and further studies are needed to elucidate this. In addition, to establish the appropriate treatment protocols in relation to the number of sessions, intensity, and application locations of treatment, additional studies will be necessary to apply diverse protocols to many patient groups and compare the effects. Given that the duration of treatment effects varied with the length of time in both groups, studies with different patient groups based on the duration of treatment and comparing the effects should also be meaningful. Finally, conducting studies with a larger number of patients would be ideal. Despite these limitations, the authors conclude that ESWT can be a useful alternative in spasticity treatment because it is noninvasive, involves much fewer adverse effects compared with existing treatment methods, and is effective in not only lower limb spasticity, as previously known, but also in gait pattern as the authors have documented in the present study.

CONCLUSIONS

SWT in combination with a conventional physical therapy exercise program may increase improvements in spasticity and gait pattern in children with hemiplegic CP.

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