

Using Radial Shock Wave Therapy to Control Cerebral Palsy-Related Dysfunctions: A Randomized Controlled Trial

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Background: Radial Shock wave Therapy (rSWT) is one of the recent promising modalities that can effectively improve muscle tone, ROM, and enhance functional capacity. It can be used to augment the rehabilitation effectiveness in spastic CP children. So, enhance their engagement in community and participation in social activities and decrease economic burden of rehabilitation.

Purpose: To investigate the effect of adding rSWT to standard physical therapy on muscular spasticity, ROM, gross motor function, and planter surface in spastic CP patients.

Methods: A total of 70 children (48 girls and 22 boys) with spastic CP were randomly assigned into the control group (n= 35 and average age 8.82±0.91) which received standard physical therapy and the rSWT group (n=35 and average age 9.0±1.81) which received the standard physical therapy plus 1500 rSWT shocks with 2 bar pressure and Hz frequency applied over acupuncture points. Passive ankle ROM, calf muscle tone, gross motor function (D and E categories), plantar surface area (PSA), and peak pressure values at midfoot (PPMF), and hindfoot (PPHF) were assessed at baseline, post-treatment, and three-month follow-up.

Results: Between-group comparisons demonstrated post-treatment statistically significant differences in ankle plantar flexion (APF), walking category of the GMFM (GMFM-E), PPHF, and PPMF with medium to high effect size values favoring the rSWTG (p=0.011, d=0.858; p=0.003, d=1.02; p=0.035, d=0.577; p=0.049, d= 0.216, respectively). At follow-up, all outcomes were statistically significantly different (p<0.05).

Conclusion: rSWT is an effective addition to the standard physical therapy care for spastic CP children in favor of spasticity, ROM, and function.

Keywords: cerebral palsy, diplegia, hypertonia, shockwave, spasticity

Introduction

Cerebral palsy (CP) is a prevalent disability that affects a significant portion of the global population. According to recent estimates, CP impacts approximately 2 to 3% of every 1000 live births.¹ CP encompasses a cluster of non-progressive neurological disorders, resulting from cerebral damage occurring at various stages—before, during, or after birth.² Clinically, CP is characterized by a diverse array of symptoms including abnormal muscular tone, impaired coordination, lack of balance, postural deviations, sensory and behavioral impairments as well as difficulties in achieving typical fine and gross motor skills.¹ The societal and economic implications of CP are substantial, with the condition presently ranking as the third most prevalent cause necessitating fundamental living support and occupying the fifth position

among the primary causes of disability. Given its intricate nature, CP poses substantial challenges for individuals affected by the condition and their families, necessitating comprehensive attention and care.

There are various types of CP. According to the muscle tone CP can be considered spastic, dyskinetic, ataxic-hypotonic, or mixed type. This classification is crucial for prognostic and interventional procedures. It is worth mentioning that children with CP might demonstrate variable types of muscular tone. For example, spastic CP child could also show mild symptoms of dyskinesia or athetosis. However, the spasticity would be the predominant feature.³

One frequent sign associated with CP is spasticity which is described as a velocity-dependent increase in muscle tone caused by upper motor neuron lesions due to the increased excitability of muscle spindles.⁴ Some authors argue that spasticity may potentially confer certain advantages to CP patients by compensating for muscle weakness.¹ Conversely, other researchers posit that spasticity constitutes a contributing factor to a spectrum of disabilities, including contractures, diminished muscular strength, and a decline in overall physical performance.² It is worth noting that spasticity can affect various regions of the body, with a common manifestation being tightness in the ankle plantar flexors, often leading to an equinus deformity in the foot.⁵ The underlying causes of such muscular tightness can be multifactorial, stemming from either muscle overactivation (referred to as the active type) or increased intrinsic connective tissue stiffness (referred to as the passive type) within the affected musculoskeletal structures.⁶ The tightness of the planter flexors decreases the plantar surface area (PSA), affects the ability of the child to stand and walk appropriately. It leads to postural deviation, abnormal weight distribution, and difficulty in maintaining balance in an upright posture which in turn might delay the achievement of many gross motor developments.⁷ The profound impact of CP on the affected individuals, their families, and the healthcare system underscores the need for comprehensive research to further investigate new intervention strategies.⁵

Treatment of muscle spasticity is quite challenging, especially in children with CP. Physical therapy, occupational therapy, medication, neuromuscular blockade, intrathecal agents, and surgery have been widely used to treat muscular spasticity.² Physical therapy has many options used traditionally to address muscular spasticity such as prolonged stretching, cryotherapy, and splinting. However, recently introduced modalities- such as shock wave therapy (SWT)- have been proven to have promising effects.⁸

SWT has emerged as a noninvasive treatment modality within the medical field, particularly for addressing chronic tendon pathologies that have proven resistant to standard physical therapy interventions.⁹ A specific variant of SWT, known as Radial shock wave therapy (rSWT) is considered a safe and easily applicable alternative to the extracorporeal type that utilizes ultrasound energy. The versatility of the SWT enables its utilization in a wide range of health problems.⁴ The mechanism underlying rSWT involves the generation of shock waves ballistically by accelerating a bullet - located inside the applicator - to hit the applicator head and transfer energy to the tissue where the kinetic energy transforms into radially expanding shock waves.¹⁰ This innovative approach to treatment holds promise as an effective therapeutic strategy for various medical conditions. However, it seems invasive, using lower pressure values along with low frequency could be quite safe for CP children who are usually demonstrating osteopenia issues and bone weakness.¹¹ Further safety could be assured if the technique was applied on a bulky muscle where direct application on bony areas is avoided.

Many researchers have argued that rSWT can stimulate the body's mechanism of healing through the facilitation of new vascularization, increasing metabolic activity, and reducing pain through the activation of the spinal gating mechanism.¹² Additionally, rSWT has been proposed to affect skeletal muscle tone through different mechanisms such as the release of nitric oxide, the signaling molecule that impedes neurotransmission in the central nervous system (CNS) and reduces spasticity.⁷ As a result, nitric oxide plays a critical role in the mechanisms that contribute to the alleviation of spasticity.¹³ These unique effects make the rSWT appropriate choice for future research compared to other traditional rehabilitation procedures.

In the context of treating muscular spasticity, rSWT was used in many circumstances.^{2,5,7,13-15} However, recent systematic reviews still recommend the application of further research either to support the use of SWT in the treatment of spasticity secondary to CP¹⁶ or to justify the use of specific shock wave parameters.¹⁷ Moreover, Ayala et al stated that conditional evidence existed regarding the use of rSWT in the treatment of muscular spasticity in children with CP, they reached this conclusion due to the limited number of research.¹⁸ Finally, some studies used a small sample size^{1,19} while other studies used a wide age range that could affect the results.²⁰

The current study targeted specific outcomes that have not been extensively studied in previous research that used rSWT. PSA along with the peak pressure values on the mid and hind feet were among the outcomes of interest. Current

study authors argue that changes in PSA and pressure distribution could be a clinical implication of improved tone that cannot be recognized by clinical tests such as the Modified Ashworth scale (MAS). These measures can reflect the improvement in ankle range of motion (ROM), stability in standing, and walking abilities of children having diplegia.

Therefore, this study aims to investigate the effect of combined rSWT and standard physical therapy on spasticity, ROM, gross motor development, PSA, and foot pressure distribution in patients with diplegia.

Methods

Study Design and Setting

This study was designed as a multi-centre, prospective, double-blind, randomized, controlled trial. The study was carried out in King Salman Centre for Disability and Hayati Centre for Daily Care, Ha'il, Saudi Arabia. The methodology was reported according to the CONSORT statement for reporting of randomized controlled trials. The recruitment procedures were consistent among all centres and based mainly on written announcements and verbal discussions with the patients.

A paediatric physical therapist with 20 years of experience in treatment and assessment of CP cases was responsible for designing the standardized treatment protocol. The same therapist was the single assessor in this study.

The research team in the three facilities adhered to a standardized treatment protocol which was designed by a paediatric physical therapist having 20 years of experience in the rehabilitation of CP. A single assessor, who was not aware of the group allocation, was designated to collect outcome measures at distinct time points, including baseline, post-treatment, and follow-up assessments.

Ethical Consideration

The current study protocol was approved by the University of Ha'il Ethical Committee (H-2023-150; date: 13-3-2023). It followed the declaration of Helsinki Guidelines.²¹ Informed consent was given by the parents before the beginning of the study. The protocol of this study was prospectively registered at clinicaltrials.gov (NCT05883020, date: 10-5-2024; status: completed; link: <https://clinicaltrials.gov/study/NCT05883020>).

Study Population

Eligible participants are those who (1) age between 8–14; (2) diagnosed with spastic diplegia; (3) able to stand alone or with assistance; (4) minimum grade of 1 on Gross Motor Function Classification System; (5) at least score 1+ on the MAS; (6) ability to attend the treatment program and the outcome assessment sessions.

The exclusion criteria were (1) children diagnosed with other types of CP as hemiplegia and quadriplegia; (2) children who received a botulinum toxin injection in the calf or any lower extremity muscle during the last six months; (3) surgery in the lower extremity during the previous year; (4) children experiencing pain in the lower limbs; (5) severe associated neurological diseases as epilepsy; (6) medications affecting peripheral muscle tones such as baclofen, clonidine, and tizanidine or anticonvulsants such as benzodiazepines, gabapentin, or peripherally acting dantrolene;²² (7) unable to communicate due to low mental functions.

Interventions

Before the start of the exercise, five meetings were conducted with all therapists - who introduced the therapeutic interventions - to ensure consistent application of the shock wave sessions and the standard physical therapy treatments. These therapists were practicing pediatric physical therapy for five years or more. Three therapists were responsible for conducting the standard physical therapy while another fourth therapist was responsible for applying the rSWT sessions. All participants received 12 sessions of standard physical therapy (3 sessions per week) while the rSWTG received an additional four sessions of rSWT (1 per week). The duration of the intervention in this study was 4 weeks.

Standard Intervention

All participants received standard physical therapy¹⁹ which consisted of regular rehabilitation procedures which consisted of:

1. 15 minutes of facilitation techniques using manual joint approximations for the ankle, knee, and hip joints.
2. 10 minutes of inhibitory techniques of any persistent primitive reflexes
3. 10 minutes of progressive strengthening of weak muscles such as hip abductors and ankle dorsiflexors using manual resistance, Thera bands or sandbags, or recreational activities.
4. 10 minutes of passive stretching exercises were applied to tight muscles such as gastrocnemius, soleus, quadriceps, hamstring, and hip adductors. Manual passive stretch was applied from a supine position and held for 30 seconds then a splint was applied if needed.
5. 15 minutes of Neurodevelopmental techniques were applied using the procedures suitable to the abilities and disabilities of each child. Exercises to facilitate sitting, standing, and walking were implemented.

Experimental Interventions

BMI-1120 SHOCK MED device (BIO-MED-INC- Italy) was used to provide the rSWT sessions. The following parameters were used: Shocks number: 1500 per muscle, applied over the belly of the calf muscle using the 15 mm applicator head. Coupling gel was applied between the tip of the applicator and the child's skin. The pressure was 2 bar, and the frequency was 4 hz. All sessions were applied while the child was in the prone position and the affected lower limb in slight knee flexion. After each session cryogel back was placed over the treated muscle for 10 minutes. The average duration of each rSWT session ranged between 6–9 minutes.

Outcome Measures

The evaluation of outcome measures in this study was performed by a single experienced paediatric physical therapist. The data collection process was conducted at baseline, after one month of therapeutic intervention, and after 3 months as a follow-up. During the initial visit, the research team conducted a comprehensive interview with the parents or guardians of the participants to elucidate the study's objectives, provide a clear explanation of its purpose, and address any inquiries or concerns raised by the parents. Subsequent assessments were administered after obtaining formal written consent from the parents or guardians, affirming their willingness to participate in the study.

Muscle Tone

For clinical assessment of spasticity, the MAS was used to assess the level of calf muscle spasticity. The assessor applied passive ankle range of motion (ROM) at various speeds on the affected side to determine the appropriate grade of spasticity.⁷ MAS grades have been described as zero if there is no increase in muscle tone, one denotes a minimal increase in tone manifested by a catch followed by low resistance throughout less than half of the range, 1+ if there is a slight increase in tone with a catch and release felt up to the half of the range, 2 indicates a marked increase in muscle tone through most of the range, but the affected part can move easily, 3 denotes a considerable increase in the muscle where passive movement will be difficult, and four if the affected part is rigid in flexion or extension. The minimal clinically important difference will be considered if at least 1-grade change in muscle tone was reported.¹⁵

Ankle Joint Active ROM

Ankle joint passive ROM was assessed with the child in the supine position and the knee of the tested lower extremity held in extension.^{1,15} To measure ROM values accurately, a conventional plastic goniometer - with a 360° protractor - was employed in this evaluation process. Goniometric assessment for ROM was proved to be a valid and reliable tool, simple and accessible.²³ The fulcrum of the goniometer was placed over the point of intersection between the long axis of the fibula and the long axis of the fifth metatarsal bone, the movable arm was placed parallel to the fifth metatarsal bone, and the fixed arm was placed parallel to the fibula. Measures of the ankle dorsiflexion (ADF) and ankle plantar flexion (APF) were recorded three times, and the average was used for the analysis.

Plantar Support Area and Peak Pressure Distribution on Mid and Hind feet

A foot scan plantar pressure detection system was used to determine several pedobarometric measurements such as PSA expressed in cm², peak pressure values at the midfoot (PPMF), and hindfoot (PPHF) expressed in kPa. This device was used for the same purpose in previous work.⁵ This device consists of a force plate (FAS system 1.0 ACP Light, Buratto

Advanced Technology, Treviso, Italy), with an active surface (47.5 × 43.0 cm) equipped with 2544 optical sensors distributed along the perimetrical border. The child was asked to assume a standing position, with or without support according to his/her abilities, looking at a fixed point, for 14 seconds. Three measures were taken for every outcome and the average was used for the quantitative analysis.²⁴

Gross Motor Function

The GMFM is widely recognized for its reliability and validity in assessing gross motor function in children with CP. It stands as one of the most effective tools for quantifying changes in the gross motor abilities of individuals with CP.²⁵ This comprehensive tool comprises 88 items distributed across five dimensions: (A) lying and rolling; (B) sitting; (C) crawling and kneeling; (D) standing; and (E) walking, running, and jumping. For this study, only dimensions D (standing) and E (walking, running, and jumping) were evaluated, which are integral components of the GMFM and contribute to a comprehensive understanding of gross motor function in children with CP. These two categories were more related to the age group of the current study sample and were investigated in previous work.⁷

The scoring system for each item is as follows: a score of 0 indicates an inability to perform the motor function, a score of 1 indicates that the completion rate is less than 10%, a score of 2 indicates a completion rate ranging from 10% to 99%, and a score of 3 indicates a full completion of the motor function.

Statistical Analysis

The statistical package of social science SPSS (version 23 for Windows) was used to analyze data. The data are presented in the format of Mean ± Standard Deviation (SD) to provide a clear summary of the central tendency and dispersion of the measured variables. The Kolmogorov–Smirnov test was used to assess the normal distribution of data. As the data were normally distributed, an unpaired *t*-test was utilized to compare the general characteristics of children in both groups as well as the outcome measures. A repeated measures ANOVA was used to assess the withing group values across the three-time point. Post hoc analyses were performed using Bonferroni test when indicated. The significance level was set at $p\text{-value} \leq 0.05$.

Sample Size

The sample size was calculated using the plantar area as the outcome of interest. The G*Power software (3.1.9.7; Heinrich-Heine-Universität Dusseldorf, Dusseldorf, Germany). Calculations based on mean and SD retrieved from previous work (Lin et al, 2018) yielded an effect size of 0.5 when the significant level = 0.05, and power = 80%. Further, the estimated desired total sample size for the study was 62 children (31 per group). A total of 70 children (35 per group) were recruited to compensate for potential dropouts.

Concealment, Randomization, and Blinding

The included children were randomly allocated to the rSWTG or CG using permuted blocks (block sizes 4 and 6) to ensure an equal 1:1 allocation ratio. The allocation sequence was performed by a researcher who was not involved in the treatment or assessment. The same researcher assigned each child a random number indicating his/her group allocation. The allocation process was concealed to all involved personnel. However, at the beginning of the study, the therapist was allowed to uncover the allocation sequence in order to introduce the proper intervention. Meanwhile, the assessor and the data analyser (statistician) remained blinded throughout the study (double-blinded design). The blinding of the statistician was achieved by masking the name of the groups using letters (T and L).

Results

A total of 70 children - diagnosed with spastic diplegic CP - met the predefined inclusion criteria and participated in this research. Each group consisted of 35 children. No dropout was reported during the intervention period or post-treatment assessment while two children in the rSWTG and one child in the CG disappeared at the follow-up due to various reasons (Figure 1) and excluded from the follow up analysis. No adverse effects were reported except mild redness over the application site of the rSWT which was resolved with cold application for 10 minutes. The two groups exhibited similarities in their basic characteristics, as indicated in Table 1.

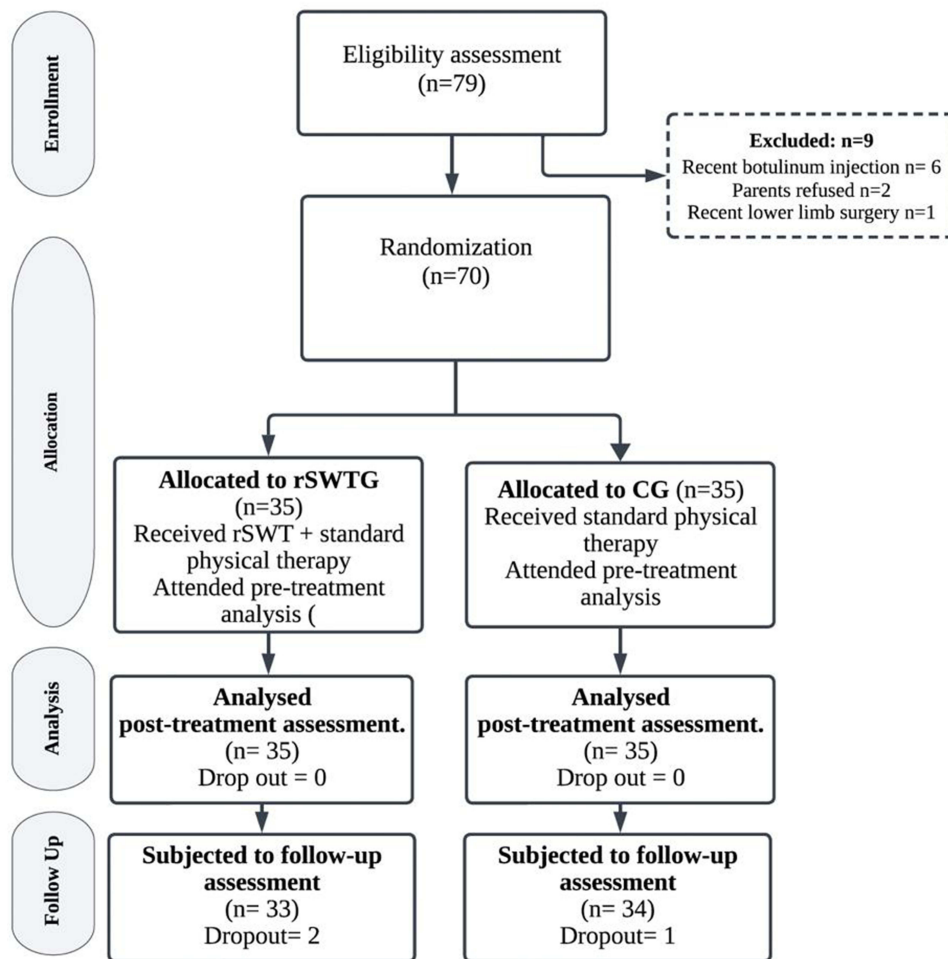


Figure 1 Flow diagram of the study.

Within-Group Comparisons

The results obtained by the one-way ANOVA with repeated measures showed statistically significantly main within-group effect regarding all outcomes in the rSWTG while in the CG the statistically significant main differences were reported in ADF, APF, GMF-D, and PSA (Table 2).

Within-Group Comparisons in the rSWTG

In the rSWTG group, there were significant differences observed in all outcome measures (ADF, APF, MAS, GMF-D, GMF-E, PSA, PPHF, PPMF) between the baseline and post treatment values ($p = 0.026, <0.001, <0.001, <0.001, 0.013,$

Table 1 Demographic Data of the Participants

Variable	Rswtg (n=35 Children)		CG (n=35 Children)		p-Value
	Mean	SD	Mean	SD	
Age year	8.82	0.91	9	1.81	0.69
Height cm	123	4.30	125	4.34	0.15
Weight Kg	27.40	4.11	28.7	7.87	0.51

Abbreviations: rSWTG, radial shock wave therapy group; CG, control group; n, number; SD, standard deviation; cm, centimeter; Kg, Kilogram.

Table 2 The Main Within-Group Analysis Using One-Way Repeated Measures ANOVA

Variable	Group	Pretreatment M±SD	Post Treatment M±SD	Follow Up M±SD	F	p	η ²
AD°	rSWTG	13.95±5.27	18.21±7.22	24.60±4.62	35.509	<0.001	0.619
	CG	10.00±12.83	16.00±10.35	19.41±10.93	9.485	0.003	0.372
AP°	rSWTG	49.04±14.54	63.60±12.57	67.60±11.92	35.405	<0.001	0.588
	CG	46.17±15.86	52.35±13.07	55.58±15.14	7.824	0.004	0.328
MAS score	rSWTG	2.43±0.92	1.65±0.91	1.69±0.74	12.415	<0.001	0.361
	CG	2.35±1.36	2.05±1.25	2.35±1.36	1.146	0.318	0.067
GMF-D score	rSWTG	63.17±12.30	69.21±10.30	72.04±10.89	23.037	<0.001	0.512
	CG	60.82±9.80	59.29±6.91	61.47±7.16	8.761	0.002	0.354
GMF-E score	rSWTG	71.08±17.49	77.52±14.02	79.26±12.42	14.293	<0.001	0.394
	CG	69.64±11.66	73.47±10.26	74.23±9.18	1.313	0.281	0.076
PSA cm ²	rSWTG	28.72±11.41	42.17±15.35	53.34±22.00	31.563	<0.001	0.589
	CG	26.41±15.17	33.76±20.47	34.97±18.82	5.919	0.011	0.270
PPHF kPa	rSWTG	62.21±19.80	89.15±33.21	93.27±30.44	13.121	<0.001	0.374
	CG	66.32±53.08	68.01±37.19	74.98±29.81	0.569	0.487	0.034
PPMF kPa	rSWTG	55.62±30.52	66.82±32.99	67.41±21.95	3.716	0.032	0.144
	CG	46.86±22.93	58.92±38.90	59.51±31.22	2.110	0.140	0.116

Abbreviations: AD, ankle dorsiflexion; AP, ankle plantar flexion; MAS, Modified Ashworth Scale; GMF, gross motor function; PSA, plantar surface area; PPHF, peak pressure in hindfoot; PPMF, peak pressure midfoot; rSWTG, radial shock wave therapy group; CG, control group; SD, standard deviation; η² Eta squared for effect size; ° degree; cm², centimeter squared; kPa, Kilo pascal.

<0.001, 0.008, 0.031, respectively). Similarly, the follow up values of the same outcomes were statistically significantly different compared to the baseline values with p values of <0.001, <0.001, 0.006, <0.001, <0.001, <0.001, <0.001, 0.022, respectively. Meanwhile, compared to the post-treatment, the follow-up values of ADF, APF, GMF-D, and PSA were statistically significantly different with p values <0.001, <0.001, <0.001, 0.004, respectively.

Within-Group Comparisons in the CG

Post treatment, the values of ADF and GMF-D were statistically significantly different compared to the baseline values (p = 0.034, 0.014, respectively). Additionally, the follow up values of the ADF, APF, GMF-D, and PSA were statistically significantly different compared to the baseline values (p= 0.011, 0.017, 0.015, and 0.013, respectively). There were no statistically significant differences between the follow-up values and those of the post- treatment (Table 3).

Between-Group Comparisons

The comparison between the rSWTG and CG revealed that baseline values for all outcomes were comparable. On the other hand, the post-treatment comparisons showed statistically significant differences in ankle APF, GMF-E, PPHF, and PPMF in favor of the rSWTG. These findings were associated with medium to high effect size (Table 3). At 3 months follow-up, all outcomes demonstrated statistically significant differences in favor of the rSWTG (Table 3). The effect size varied from high as found in GMF-F ($d=1.08$) and low as found in the ADF ($d=0.249$).

Table 3 Within and Between-Group Comparisons at Baseline, Post-Treatment, and Follow-up

Variable	Time	rSWTG M ± SD	CG M ± SD	MD	95% CI		T	P	d
					Lower	Higher			
AD°	Baseline	13.95±5.27	10.00±12.83	3.95	-0.72	8.62	1.30	0.201	0.081
	Pos-intervention	18.21±7.22*	16.00±10.35*	2.21	-2.04	6.45	0.777	0.442	0.249
	Follow up	24.60±4.62*¥	19.41±10.93*	5.19	1.18	9.19	1.99	0.047	0.638
AP°	Baseline	49.04±14.54	46.17±15.86	2.87	-4.38	10.12	0.578	0.567	0.120
	Pos-intervention	63.60±12.57*	52.35±13.07	11.25	5.13	17.36	2.68	0.011	0.858
	Follow up	67.60±11.92*¥	55.58±15.14*	12.02	5.52	18.51	2.73	0.012	0.857
MAS score	Baseline	2.43±0.92	2.35±1.36	0.8	-0.47	0.63	0.220	0.827	0.114
	Pos-intervention	1.65±0.91*	2.05±1.25	0.4	-0.12	0.92	-1.15	0.256	0.369
	Follow up	1.69±0.74*	2.35±1.36	0.66	0.13	1.18	-1.89	0.046	0.606
GMF-D score	Baseline	63.17±12.30	60.82±9.80	2.35	-2.95	7.65	0.287	0.776	0.162
	Pos-intervention	69.21±10.30*	59.29±6.91*	9.92	5.73	14.10	0.983	0.332	0.314
	Follow up	72.04±10.89*¥	61.47±7.16*	10.57	6.17	14.96	1.37	0.041	0.439
GMF-E score	Baseline	71.08±17.49	69.64±11.66	1.44	-5.65	8.53	0.63	0.530	0.132
	Pos-intervention	77.52±14.02*	73.47±10.26	4.05	-1.81	9.91	3.19	0.003	1.02
	Follow up	79.26±12.42*¥	74.23±9.18	5.03	-0.17	10.23	3.39	0.002	1.08
PSAcm ²	Baseline	28.72±11.41	26.41±15.17	2.31	-4.09	8.71	0.535	0.595	0.111
	Pos-intervention	42.17±15.35*¥	33.76±20.47	8.41	-0.22	17.04	1.44	0.156	0.453
	Follow up	53.34±22.00*¥	34.97±18.82*	18.46	8.60	28.13	2.70	0.010	0.862
PPHF kPa	Baseline	62.21±19.80	66.32±53.08	4.11	-14.99	23.21	-0.332	0.742	0.171
	Pos-intervention	89.15±33.21*	68.01±37.19	21.14	4.32	37.95	1.84	0.035	0.577
	Follow up	93.27±30.44*¥	74.98±29.81	18.29	3.91	32.66	1.84	0.039	0.579
PPMF kPa	Baseline	55.62±30.52	46.86±22.93	8.76	-4.11	21.63	0.969	0.339	0.110
	Pos-intervention	66.82±32.99*¥	58.92±38.90	7.9	-9.30	25.10	0.675	0.049	0.216
	Follow up	67.41±21.95*¥	59.51±31.22	7.9	-4.97	20.77	0.915	0.043	0.293

Notes: *Statistically significant compared to baseline at $p < 0.016$. ¥Statistically significant compared to post treatment at $p < 0.016$.

Abbreviations: AD, ankle dorsiflexion; AP, ankle plantar flexion; MAS, Modified Ashworth Scale; GMF, gross motor function; PSA, plantar surface area; PPHF, peak pressure in hindfoot; PPMF, peak pressure midfoot; rSWTG, radial shock wave therapy group; CG, control group; SD, standard deviation; d, Cohen's d value for effect size; °, degree; cm², centimeter squared; kPa, Kilo pascal.

Discussion

This study aimed to assess the therapeutic effects of adding rSWT to standard physical therapy treatment on active ROM of the ankle joint, muscular spasticity, GMF (D and E categories), PSA, and pressure distribution on the mid and hind foot in children with spastic diplegic CP. After four weeks of treatment, APF, GMF-E, PPHF, and PPMF were better in the rSWTG compared to the control. At follow-up, all outcome measures were better in the rSWTG compared to the control. This suggests that the rSWTG was effective in improving ROM, muscle tone, GMF, PSA, and peak pressure distribution on mid and hind feet. These favorable effects were more evident after three months of the intervention.

Previously published research is plenty. However, many studies did not use the radial type of shock wave.^{1,19,24,26} Other studies that used the radial type of shock wave demonstrated variations in the assessed outcomes. For example, the assessment of muscle tone using MAS was a common outcome measure.^{2,5,7,15} The second commonly used outcome measure was the function which was assessed mainly using GMFM-88.^{5,7,15} On the other hand, less number of studies investigated ankle ROM^{2,15} and the area of plantar surface or pressure distribution on the sole of the feet.^{5,13}

Regarding muscle tone, the current findings were supported by those observed previously by Kwon and Kwon where calf muscle tone reduced significantly after application of gastrocnemius botulinum toxin injection plus rSWT.² Similar findings were reported by other studies either on the calf muscle^{7,15} or on other muscles such as hamstrings and triceps.⁵ Interestingly, after a single session, Gonkova et al reported a significant reduction in muscle spasticity measured by

MAS. This reduction lasted for 4 weeks after the application of rSWT.¹³ Interestingly, significant muscle tone findings were also observed when the rSWT was applied to the spastic muscles as well as to its antagonistic. According to Vidal and colleagues, these positive findings lasted for more than two months after treatment.¹⁴ In Vidal's study, different spastic muscles were treated such as biceps, wrist flexors, hip adductors, hamstrings, and calf muscles.

Regarding function, Emara and colleagues⁷ assessed the D and E categories of the GMFM-88 on a group of children having unilateral CP. The children who received rSWT demonstrated significant improvement in the D category of the GMFM while there was no significant difference in favor of the E category which could be attributed to the younger age groups compared to the current study. Moreover, two additional studies^{5,15} found more improvement in the GMFM-88 measures in the children who received rSWT compared to the control. In the Wang and colleagues' study,¹⁵ the score of the GMFM was age-dependent which might explain the difference in GMFM E category between the current study and Emara's.⁷ Lin et al supported these findings as well.⁵

Regarding ROM, there was a common agreement among the previous studies as well as the current one that applying rSWT over spastic calf muscle in combination with standard treatments is beneficial in improving ankle joint ROM.^{2,15} Moreover, Vidal et al observed similar beneficial effects when rSWT was applied to the antagonistic muscle.¹⁴ The data of a small sample (n=15) was retrospectively collected by Kwon and Kwon and was analyzed to reveal that botulinum toxin and rSWT can improve ankle dorsiflexion, while no data regarding ankle plantar flexion was assessed.² Similarly, Wang et al reported significant improvement in ankle passible dorsiflexion after the application of rSWT which was evident after treatment and at 3 months follow up as reported in the current study.¹⁵

Regarding the area of the plantar surface and the pressure distribution, two previous studies assessed PSA and the distribution of pressure on the plantar area of the affected feet. Lin et al assessed the PSA and plantar pressure after two and four weeks of rSWT and standard treatment where both values continued to improve in the groups that received rSWT compared to the control one. The children in Lin's study were those who underwent multistage corrective surgeries for tendon release such as including hip adductor muscle lysis, hamstring lysis, and Achilles tendon contracture-releasing surgery.⁵

The other study that was conducted by Gonkova and colleagues¹³ reported significant improvement in the PSA measured while the child walked on the force platform. They also reported significant improvement in the peak pressure exerted on the heels measured while the child was in a standing position. These findings support ours. However, in the current study, the PSA and peak pressure on the mid and hind feet were measured while Lin et al assessed PSA only and Gonkova et al did not measure the PPHF. Improvement in the PSA and the distribution of pressure could improve the ability to stand in a more optimal alignment, increase the base of support and stability. This improvement could have a positive implication for the further motor achievements regarding standing ability and ambulation skills.¹³

The mechanism by which rSWT improves muscle tone has been a topic of interest among researchers, and while there is no definitive explanation, several hypotheses have been proposed.^{14,27} One theory suggests that the release of nitric oxide may be involved.⁷ Nitric oxide is a signaling molecule that has diverse functions in the body, including a role in neural transmission in the CNS. The secretion of nitric oxide as a result of rSWT promotes the development of neuromuscular junctions. Nitric oxide has important functions in memory, neural transmission in the CNS, and reducing spasticity by impeding neuromuscular transmission. As a result, nitric oxide plays a critical role in the mechanisms that contribute to the alleviation of spasticity.¹³ Another explanation can be attributed to the direct mechanical effect of rSWT on specific structures inside skeletal muscle such as Golgi tendon organs which might decrease the facilitatory impulse coming from the CNS and reduce muscle tone.⁴ While the exact mechanisms are not yet fully understood, Further research is needed to elucidate the precise mechanisms involved and to better understand the therapeutic benefits of rSWT in CP.

Improvement in GMF especially the D category of the GMF-88 scale can be partially attributed to the improvement in calf muscle tone and consequently the ability of the feet to receive body weight more efficiently. This finding was supported by the higher values of PSA, PPHF, and passive ROM values seen in the children who received rSWT compared to the control. One of the possible explanations for the current findings is the improvement in the connective tissue stiffness, acting on fibrosis of chronic hypertonic muscles. These findings were reported in previous studies that investigated the effects of SWT on different musculoskeletal problems.^{22,28}

It is worth mentioning that the commonly used rSWT parameters reported in the current study as well as the previous work that has been proven to be effective are as follows, 1500 shock wave hits, 4 hz frequency, 2 bar, 15mm head diameter, and

application site over the muscle belly.^{2,5,7,13-15} Other less commonly used parameters were 2000 hits,⁵ 5,¹³ 8,¹⁵ and 10 Hz⁵ frequency, hit pressure of 0.6¹⁵ or 1.5¹³ bar that necessitates future work to justify the most appropriate rSWT parameters that can be the best choice in treating spastic muscle secondary to CP.

The beneficial effects seen in the current study and their support from previous work should be reflected in clinical practice. Pediatric rehabilitation facilities that deal with CP children as well as pediatric physical therapists should incorporate the use of the rSWT technology in their practice in order to achieve better clinical and functional results and optimize the success of the physical therapy program.

It is important to acknowledge that this study has certain limitations that should be considered when interpreting the results. The therapist responsible for administering the treatment was not blinded to the group assignments, potentially introducing bias into the results. However, the experience of the assessor could reduce any potential bias. The follow-up period of three months might be considered short when investigating CP, which is a life-long condition. Longer-term follow-up assessments could provide a more comprehensive understanding of the treatment's effects over longer time scale. The study involved a relatively small number of rSWT sessions (n=4), which may not have fully revealed the therapeutic potential of this intervention, particularly in outcomes such as GMF D. Future studies with a greater number of treatment sessions could provide a more comprehensive assessment of rSWT's effectiveness.

Conclusions

In light of the current findings, the combination effect of rSWT - on spastic calf muscles -plus the standard physical therapy in children with spastic diplegia appears to be a promising and advisable option. The results of this study indicate that rSWT can lead to significant improvements in various important outcomes, including ROM, spasticity, Gross Motor Function, and pressure distribution on the feet when integrated in clinical practice. These positive outcomes should be subjected to further investigations to establish the long-term therapeutic effects on children with spastic CP.

Abbreviations

CP, Cerebral palsy; SWT, shock wave therapy; rSWT, radial shock wave therapy.; MAS, Modified Ashworth scale; AD, ankle dorsiflexion; AP, ankle plantar flexion; PSA, Plantar surface area;; PPMF, Peak pressure values at the midfoot; PPHF, Peak pressure values at the hindfoot.

Data Sharing Statement

Data for the current study will be available upon reasonable request from the principal investigator or corresponding author.

Ethics Approval and Consent to Participate

This study was conducted per the Declaration of Helsinki and was approved by the University of Ha'il ethical committee and the Ha'il region ethical committee on 13-3-2023.

Acknowledgments

This research has been funded by the Scientific Research Deanship at the University of Ha'il - Saudi Arabia, under project number RG- 23247.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This research was funded by the Scientific Research Deanship at the University of Ha'il - Saudi Arabia, under project number RG- 23247.

Disclosure

We declare that we have no financial or personal relationships among the authors that could potentially influence or bias the content of this study.

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