Original article

Clinical Assessment and Pedobarographic Analysis after Radial Shock Wave Therapy of Ankle Plantar Flexor Spasticity in Stroke

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Abstract

Objective: Radial shock wave therapy (RSWT) has increasingly been utilized in the treatment of spasticity recently. The purpose of the current study is to assess the effectiveness of RSWT in the treatment of ankle plantar flexor muscles spasticity of stroke patients by pedobarography and clinical evaluation. Materials and Methods: A total of 23 stroke patients were enrolled into the study. Patients received an initial sham treatment of RSWT, followed by three separate interventional sessions received one week apart. Treatment success was assessed using the Modified Ashworth Scale (MAS), ankle passive range of motion (pROM) measurement and pedobarography. Results and Discussion: No significant change was observed in clinical and pedobarographic values following sham RSWT. In the intervention group, however, MAS decreased from 3.34±0.7 to 2.39±0.89 after a single RSWT session and to 2.04±0.92 first week and to 2.52±0.89 fourth week after three RSWT sessions. As a result of the study, heel peak pressure and total plantar contact area were improved. In particular, three RSWT sessions were more effective than single RSWT session. Conclusions: We observed a significant improvement in plantar flexor spasticity in stroke patients after both a single and three RSWT sessions and this improvement persisted during the four-week study period.

Keywords: shock wave therapy; spasticity; stroke

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Introduction

Stroke related spasticity can occur in extremities, thereby reducing functionality and increasing patient dependence ¹. Lower extremity spasticity, particularly in the ankle plantar flexor muscles, causes instability, impairs ambulation and may cause knee pain due to the hyperextension of the knee ². Additionally, energy expenditure is higher in stroke patients ³. The main goal of the treatment for spasticity is to provide functional improvement

in stroke patients. Treatment options are diverse but, particularly, includes systemic anti-spasticity drugs in patients with widespread spasticity and phenol or blockade with botulinum toxin in patients with focal spasticity ⁴. Although generally, the clinical outcomes with botulinum toxin are reported to be successful, inadequate dosage or drug resistance may lead to treatment failure in some patients.

Recently, shock wave therapy (SWT) has been found to be beneficial in patients with spasticity,

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but the underlying mechanism is still unknown ^{5, 6}. Depending on the wave propagation, shock wave treatment is divided into two categories: extracorporal shock wave therapy (ESWT) and radial shock wave therapy (RSWT). Compared with ESWT, RSWT is less painful, less expensive and has lower energy flux density values ⁷⁻⁹. In recent years, SWT has been used frequently in the treatment of spasticity in stroke patients ¹⁰. In a previous study, researchers even made a comparison of focus and radial SWT and they found that therapies resulted in similar significant decreased in spasticity ¹¹.

The Modified Ashworth Scale (MAS), among many others, is the most frequently used assessment scale in patients with spasticity. However, depending on the examiner, MAS may yield subjective results ¹². Pedobarography which may be used as an indirect measurement of ankle spasticity, provides objective results and has previously been shown to be a useful modality to evaluate the effectiveness of spasticity treatment in patients with cerebral palsy ^{9, 13}.

The aim of this study is to investigate the effectiveness of RSWT in the treatment of plantar flexor spasticity in stroke patients using both clinical parameters and pedobarographic examination.

Materials and Methods

This study was conducted between April 2014 and April 2015.

Patients

A total of 23 stroke patients aged between 18 and 80 presenting with ankle plantar flexor muscles spasticity were enrolled into the study. Written informed consent was obtained from all the patients and their relatives prior to enrollment. The study was realized in accordance with the Helsinki Declaration principles.

Inclusion criteria were patients with an ankle spasticity score ≥1+ according to MAS, duration of a stroke more than 3 months and sufficient cognitive functions. Patients with a history of repetitive stroke, those who could not stand without support, patients using anticoagulants and those who were administered botulinum toxin in the last 6 months were excluded from the study. The dosages of the antispasticity drugs were not changed during the study period. Patients treated with RSWT, also received neurologic rehabilitation, but not ankle stretching exercises. Demographic characteristics of the patients (age, sex, and educational status), etiology of stroke, side of hemiplegia, disease duration and list of medication was recorded.

RSWT protocol

Patients received an initial sham treatment of RSWT, followed by three separate sessions received one week apart (Swiss Dolorclast, EMS, in Switzerland). Both sham and interventional RSWT procedures were given in prone position. The intervention group received RSWT following the application of a conductive gel on the plantar flexor. The RSWT procedure was applied 4000 shocks on the gastrosoleus muscles by using 10 mm applicators at a rate of 5 Hz at 2 bar and total 0,28 mj/mm² energy flux density. The application was discontinued in patients who reported pain. Each session was scheduled for 15 minutes.

Clinical and pedobarographic assessment

An examiner blinded to the study protocol performed the clinical and pedobarographic assessment at baseline (P1) (pre-sham RSWT), one week later the post sham RSWT (Pre-RSWT) (P2), one week after the first RSWT session (P3) and one week (P4) and four weeks (P5) after the third RSWT session (Figure 1).

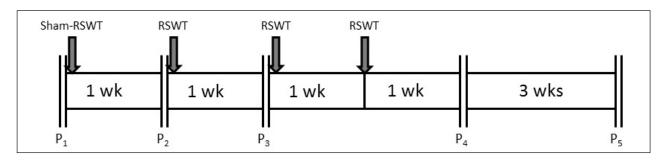


Figure 1: Study procedure.

Clinical assessment

The spasticity of the plantar flexors were assessed with MAS. The passive range of motion (pROM) of the ankle was measured using a manual goniometer. All examinations were performed while the patients were lying on their beds with their knees were in extension. The ankle pROM was determined by taking the average of three respective examinations.

Pedobarographic evaluation

Static and dynamic pedobarographic evaluations were performed using pedobarography (Rs Scan-Footscan®, Belgium). During static measurement patients were asked to put their hands by their sides, hold their heads upright and look straight ahead. Measurements were performed after at least one minute of standing upright. Heel peak pressure was recorded as N/cm2. Dynamic measurements were performed while the patients were on the walking platform of the pedobarography and measurements were conducted after patients walked for twice to obtain normal walking speed and rhythm. Patients were assisted when necessary and breaks were given when patients complained of exhaustion. Total plantar surface area was measured as square centimeter (cm²). Static measurements were performed two times and dynamic measurements for four times; averages were taken for both assessments and final analyses were performed. Increase in the heel peak pressure and plantar surface area is accepted as an indirect measure of a decrease in the plantar flexor spasticity 9.

Statistical analyses

Statistical analyses were performed using the Statistical Package for the Social Sciences software (IBM version 20.0; SPSS Inc., Chicago, USA). The distribution of the variables was assessed using visual (histogram and probability graphics) and analytic methods (Kolmogorov-Smirnov / Shapiro-Wilk tests). Descriptive statistics including demographic characteristics, MAS, pROM and pedographic findings were presented as mean ± Standard deviation. Comparisons between pre-and post sham-RSWT, and between pre-and post interventional RSWT applications were performed using the Wilcoxon Signed Rank test. Correlation between MAS and pedographic findings was assessed using the Spearman correlation test. Statistical significance was set at p < 0.05.

Ethical clearance:

Afyon Kocatepe University Health Research Ethics Committee approval was obtained prior to study start

Results

Demographic characteristics are presented in Table 1.

Table 1: Demographic characteristics of the subjects.

Age (year)	55.13±11.15
Sex (Female: Male) (%)	7:16 (30.4%:70.6%)
Disease duration (month)	18.34±11.55
Etiology (Ischemia:Hemorrhage) (%)	16:7 (70.6%:30.4%)
Lesion site (Right:Left) (%)	11: 12 (47.8%:52.2%)

Values are presented as mean±standard deviation.

Clinical assessments

Modified Ashworth Scale

We did not observe a significant difference in MAS scores in the sham group (Table 2). In the intervention group, however, the spasticity scores decreased from 3.34±0.7 at P2 to 2.39±0.89, 2.04±0.92, and 2.52±0.89 at P3, P4, and P5, respectively (Table 3). Additionally, the spasticity score after the third RSWT session was significantly lower as compared with the score after a single RSWT session (p=0.005). Although spasticity score showed an increase at P5 after P4, the difference was not significant (p=0.510) (Table 3).

Ankle passive range of motion

Ankle pROM did not show a significant change following Sham RSWT (Table 2). In the intervention group, however, it increased from 45.43±8.10° at P2 to 54.34±7.27° at P3 and further to 56.52±8.31° and 55.00±8.91° at P4 and P5, respectively (Table 3). Additionally, although not significant, pROM at P4 (following three RSWT sessions) was higher than at P3 (following a single RSWT session) (p=0.059) (Table 3).

Pedobarographic assessment

The difference in heel peak pressure and total plantar contact area were not significantly different between measurements obtained at P1 and P2 (Table 2). Heel peak pressures were significantly increased at P3 after P2 and at P5 after P4, but not at P4 after P3 (p= 0.123) (Table 3). According to the Spearman correlation test there was a significant and negative correlation between MAS scores and heel peek pressures at P1, P2, P3 and P5 (Table 4) but not at

P4 (r= -.381, p=0.073). The pedographic findings of a patient with left-sided hemiplegia is presented in Figure 2. The total plantar contact area levels were significantly higher at P4 and P3 but not at P5 when compared with P2. Additionally, no difference was observed between P3 and P4 measurements (p= 0.637) (Table 3). No correlation was observed between MAS scores obtained at P1, P2, P3, P4 and P5 and total plantar contact area levels (Table 4). Dynamic pedographic values of a patient with leftsided hemiplegia are presented in Figure 3.

Table 2: Clinical and pedabarographic findings of Pre and Post-Sham RSWT

Variables		Pre-Sham RSWT RSWT		p values	
MAS		3.34±0.71	3.34±0.71	1.000	
pROM (°)		44.56±8.10	45.43±8.10	0.157	
	Peak pressure of heel (N/cm²)	83.10±30.51	85.76±31.78	0.088	
PDB	Foot contact area (cm²)	151.56±25.58	150.62±25.23	0.738	

Values are presented as mean±standard deviation.

MAS: Modified Ashworth Scale, pROM: Passive Range of Motion,

PDB: Pedobarography, RSWT: Radial Shock Wave Therapy

Table 3: Clinical and pedobarographic findings of Pre and Post RSWT

Variable	s	Pre-RSWT	1. week after single RSWT session	1. week after three RSWT sessions	4. week after three RSWT sessions	p*	p#	pł	рΦ	p ^χ
MAS		3.34±0.71	2.39±0.89	2.04±0,92	2.52±0.89	<0.001	<0,001	< 0.001	0.510	0.005
pROM ((°)	45.43±8.10	54.34±7.27	56.52±8.31	55.00±8.91	<0.001	<0.001	0.001	0.178	0.059
	Peak pressure of heel (N/cm²)	85.76±31.78	100.56±24.85	96.13±21.20	96.62±26.59	0.001	0.022	0.005	0.862	0.123
PDB	Foot contact area (cm²)	150.62±25.23	156.05±19.12	157.28±18.59	156.23±18.85	0.035	0.026	0.140	0.273	0.637

Values are presented as mean±standard deviation.

MAS: Modified Ashworth Scale, pROM: Passive Range of Motion, PDB: Pedobarography, RSWT: Radial Shock Wave Therapy

p*: p value of comparison between the Pre-RSWT and 1. week after single RSWT session

p#: p value of comparison between Pre-RSWT and 1. week after three RSWT sessions

pl: p value of comparison between Pre-RSWT and 4. week after three RSWT sessions

 $p\Phi$: p value of comparison between 1. week after three RSWT sessions and 4. week after three RSWT sessions

px: p value of comparison between 1. week after single RSWT session and 1. week after three RSWT sessions

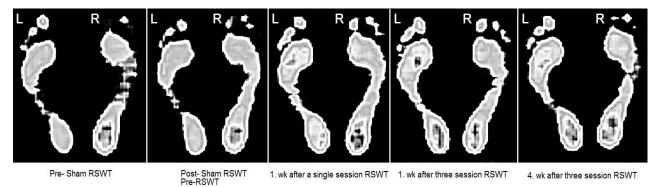


Figure 2: Static pedobarographic findings (Peak Pressure of Heel) of a patient with left

Table 4: Spearman correlation analysis between MAS and pedobarographic data

MAS- Peak pressure of heel	n	r	p
Pre-Sham RSWT	23	579	0.004
Pre-RSWT	23	674	<0.001
1. week after single RSWT session	23	609	0.002
1. week after three RSWT sessions	23	381	0.073
4. week after three RSWT sessions	23	562	0.005
MAS- Foot contact area			
Pre-Sham RSWT	23	291	0.178
Pre-RSWT	23	299	0.165
1. week after single RSWT session	23	169	0.440
1. week after three RSWT sessions	23	203	0.354
4. week after three RSWT sessions	23	024	0.912

MAS: Modified Ashworth Scale, RSWT: Radial Shock Wave Therapy

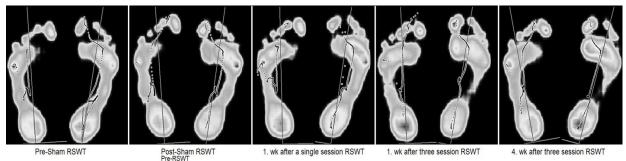


Figure 3: Dynamic pedobarographic findings (Total plantar contact area) of a patient with left hemiplegia. The images show to increase contact area at the left foot and improvement in stance phase.

Discussion

In the current study, using clinical and pedographic examination, we assessed the effectiveness of RSWT in stroke patients with plantar flexor spasticity. The decrease in spasticity documented after both a single and three RSWT sessions and its persistence during the four-week study period were the most significant findings of the study. We did not observe any change in clinical and pedographic values following sham RSWT. No treatment related adverse effects were observed.

Spasticity associated with stroke generally affects the flexor muscles of the upper and extensors of the lower extremity. In the lower extremity, spasticity is more prominent in the thigh adductors, knee extensors, plantar flexors and supinators ¹⁴. Treatment is either pharmacologic (anti-spasticity agents, injections etc.) or non-pharmacologic (physical treatment modalities, surgery etc.) ¹⁵. Alternatively, shock wave treatment has also been increasingly used in the treatment of spasticity recently. A standard treatment protocol comprising the intensity, pulse range,

and number of treatment sessions for shock wave therapies, however, has not yet been established. The effectiveness of SWT has previously been assessed in stroke patients with various clinical presentations 10, ¹⁶⁻²⁰. In current study we applied three RSWT sessions 4000 shots 0,28 mj/mm² energy flux density to plantar flexors. In all these studies, SWT was applied with different energy densities, durations, frequencies and number of sessions. However, it has been reported that the effectiveness of shockwave therapy depends on the energy density reaching the target area ²¹. It is thought that the energy density reaching the target area is not related to the duration of treatment or the frequency of shock waves 10. In our study, we achieved improvement in spasticity despite treatment with different duration and frequency compared to other studies. Nevertheless, what is the minimum energy density that reduces spasticity is unknown.

The mechanism of shock waves on spasticity has not been fully elucidated yet. Kenmoku et al., in an experimental study on rats, demonstrated that shock waves induced degeneration of the acetyl choline receptors and reduced their numbers at the neuromuscular junction; consequently, impairing neurotransmission ²². Bae et al. Suggested that shock waves inhibited the activities of the Golgi tendon organ and thereby impaired the excitability of the motor nerves ²⁰. Although the effect of SWT on the spasticity is unknown, it is thought to be effective by reducing fibrosis in the spastic muscle ¹⁰. Others postulated that shock waves may modulate nitric oxide production and thereby trigger anti-inflammatory actions and relieve pain by inhibiting pain inducing substances ^{23, 24}.

Although RSWT has consistently been shown to be effective in the treatment of spasticity, the duration of the beneficial effects remains poorly defined. In the current study, MAS spasticity scores, following a single RSWT application, were significantly lower at one week. Furthermore, we demonstrated that three sessions of RSTW as compared with a single session, further reduced MAS scores at one week. Our findings are in contrast with Bae et al. 21 who failed to show a reduction in MAS scores at one week. This discrepancy may be, in part, explained by the differences in the density of therapy and the affected muscles. Reseraches that evaluated the effectiveness of SWT in the long term yielded conflicting results. The longest followup period between study evaluating the efficacy of shock waves on spasticity was 12 weeks. While Manganotti et al. 16 demonstrated that the effect of ESWT persisted even after 12 weeks, Santamato et al.²⁵, in a study where in patients received concurrent botulinum toxin injection, did not find a significant difference between MAS scores assessed at the start of the treatment and at 12-week post-treatment. Gonkova et al. 9, in a study conducted on patients with cerebral palsy, showed that the effectiveness of RSWT persisted for four weeks. In the current study, we demonstrated that the effectiveness of three RSWT sessions, although declining, persisted for four weeks. More accurate estimations on the duration of ESWT may be given following a better understanding of the mechanism of the shock waves on spasticity.

Spasticity was evaluated by measuring the contact area and heel peak pressure with pedobarography. In the previous study has measured plantar contact area by force plate in stroke patients. They reported that the plantar contact area was contrary correlated with spasticity during gait and increased after RSWT ¹¹. Generally, pedobarography was preferred to evaluate

plantar flexor spasticity in cerebral palsy patients 9,26, ²⁷. A number of studies, so far, have shown an increase in heel peak pressure and plantar contact area, lasting for up to four weeks, following a reduction in spasticity using shock waves. Additionally, these studies have also demonstrated an improvement in postural stability and ambulation 9,13. In two separate studies conducted on patients with cerebral palsy who had spastic dynamic equinus foot, botulinum injection for spasticity resulted in an increase in heel peak pressures and total plantar contact areas, as assessed on pedobarography ^{26, 27}. Similarly, in the current study, we found a sustained increase in heel peak pressure over four weeks, following RSWT application. While the plantar contact area also demonstrated a significant increase at one week after RSWT treatment, the difference was no more significant at week four. Finally, we also found a negative correlation between heel peak pressures and MAS scores.

This study has limitations. The sample size was relatively small and long-term results of RSWT were not evaluated. Additionally, we did not assess the efficacy of different energy flux densities.

Conclusion

RSWT, which is a noninvasive treatment modality with relatively few adverse effects, may be considered as an alternative treatment in patients with lower extremity spasticity. Additionally, future studies should consider using pedobarography in the assessment of ambulation and balance in stroke patients with spasticity and should also assess the effectiveness of different energy flux densities.

Conflict of Interest

The authors declared no conflict of interest.

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There were not received funding/support for this article from anywhere.

Author's contribution

Data gathering and idea owner of this study: Dikici Ö, Solak Ö, Ulaşlı AM

Study design: Dikici Ö, Solak Ö, Ulaşlı AM

Data gathering: Dikici Ö, Eroğlu S; Toktaş H, Dündar Ü

Writing and submitting manuscript: Dikici Ö, Ulaşlı AM

Editing and approval of final draft: Dikici Ö, Solak Ö, Ulaşlı AM, Eroğlu S, Toktaş H, Dündar Ü

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