



**Original Article** 

# Effectiveness of radial extracorporeal shock wave therapy in post-stroke spasticity patients: Evaluation with shear wave elastography

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### ABSTRACT

Objectives: This study aimed to evaluate the effectiveness of radial extracorporeal shock wave therapy (ESWT) in treating spasticity in post-stroke patients using shear wave elastography (SWE).

Patients and methods: This randomized controlled trial was conducted with 42 patients (29 males, 13 females; mean age: 64.0±8.5 years; range, 47 to 80 years) between June 2022 and August 2023. Stroke patients with biceps muscle spasticity were randomly assigned to either an active ESWT treatment group or a control group. Both groups underwent conventional rehabilitation programs. The ESWT group received four treatment sessions once a week for four weeks. Primary assessment criteria included SWE measurement values. Secondary criteria included the Modified Ashworth Scale, Modified Tardieu Scale, Fulg-Meyer Upper Extremity Assessment, and Functional Independence Measures. Evaluations were performed before treatment, immediately after treatment, one month after treatment, and three months after treatment.

Results: In the ESWT group, significant decreases in Modified Ashworth Scale and Modified Tardieu Scale scores observed one month after treatment were not maintained at three months. Improvements in Fulg-Meyer Upper Extremity Assessment and Functional Independence Measures scores were noted immediately after treatment and at one and three months after treatment, whereas these improvements were only observed at three months in the control group. Significant decreases in SWE measurements at 90° flexion and 180° extension observed one month after treatment in the ESWT group were not sustained at three months.

Conclusion: Our study highlights the short-term efficacy of ESWT as an adjunct to conventional rehabilitation in reducing spasticity in post-stroke patients with biceps muscle involvement. The correlation of SWE with physical examination methods emphasizes its potential role in the assessment and follow-up of spasticity treatment.

Keywords: Elasticity imaging techniques, extracorporeal shockwave therapy, spasticity, stroke.

Spasticity, commonly observed after stroke, ranks among the complications that significantly affect the functional recovery of patients.[1] According to a meta-analysis, the incidence of post-stroke spasticity is 25.3%. Spasticity develops in 39.5% of patients who experience their first stroke with hemiparesis, and 9.4% of these cases exhibit severe spasticity.<sup>[2]</sup>

Various methods are employed for the effective management of spasticity, including physical therapy agents, rehabilitation techniques, pharmacological agents, and local injections. However, the evidence for existing treatment options is not sufficient, leading to ongoing efforts to explore new therapeutic

approaches. In recent years, there has been increased interest in noninvasive treatment modalities, such as extracorporeal shock wave therapy (ESWT).

Although the exact mechanism of ESWT's effect on spastic muscles is not fully understood, some mechanisms have been suggested. Extracorporeal shock wave therapy is believed to increase nitric oxide synthesis, promoting neovascularization in muscles and tendons. Additionally, it is thought to play a role in synaptic plasticity, triggering the formation of new neuromuscular connections. It has also been proposed that ESWT can reduce alpha motor neuron excitability through tendon pressure. Some studies

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Received: February 09, 2024 Accepted: September 04, 2024 Published online: December 27, 2024

Cite this article as: Özbek İC, Tıkız C. Effectiveness of radial extracorporeal shock wave therapy in post-stroke spasticity patients: Evaluation with shear wave elastography. Turk J Phys Med Rehab 2025:71(x):i-x, doi: 10.5606/tftrd.2025.14800.



ii Turk J Phys Med Rehab

have shown a decrease in acetylcholine receptors at the neuromuscular junction and a temporary impairment of nerve conduction. Among the nonneural effects of ESWT are a decrease in fibrosis in hypertonic muscles and the correction of rheological properties. [3] These studies support the evaluation of ESWT as a potential treatment modality for spasticity.

Ultrasonography is a rapid, cost-effective, and noninvasive evaluation method that avoids radiation exposure. It provides real-time and dynamic assessment, guiding physiatrists in diagnosis and interventional procedures.[4] In recent years, ultrasound elastography used in the evaluation of muscle spasticity, particularly shear wave elastography (SWE), has gained attention. Shear wave elastography measures the speed of shear waves created by acoustic radiation force impulses to assess tissue elasticity. In SWE, apart from velocity measurements, elastograms are created in compression elastography. Quantitative data on the elasticity of the tissue are obtained by measuring the shear wave velocity (m/sec) in the area determined using the region of interest.[5] The shear wave velocity values of hard tissues are higher.[6]

In the literature, studies investigating the use of ESWT in the management of post-stroke muscle spasticity present varying results regarding the effectiveness of ESWT in reducing spasticity and improving functional outcomes in stroke patients. Some studies observe significant short-term benefits immediately and within 24 h after treatment, while the results on long-term effectiveness are inconsistent. Although many studies report improvements at the one-month follow-up after treatment, some indicate that the benefits observed during the acute phase diminish by the first-month follow-up.[8-21] Studies involving long-term follow-up are quite limited, and their results also vary. Furthermore, the optimal parameters for ESWT, including the frequency, intensity, and duration of treatment, have yet to be standardized.<sup>[7]</sup> Despite these differences and uncertainties, the increasing interest in noninvasive therapies such as ESWT highlights the need for further research to elucidate their potential advantages and limitations in poststroke spasticity treatment.

This study aimed to evaluate the efficacy of radial ESWT (rESWT) in the treatment of spasticity in the biceps muscle after stroke using both traditional physical examination methods and quantitative SWE. Furthermore, this study sought to provide insights into the short-term and potentially long-term outcomes of

ESWT in the management of spasticity after stroke. Unlike other studies in the literature, this study incorporated SWE. In addition, as one of the few studies with long-term follow-up, it aimed to contribute to the existing research literature by providing data on the sustainable effects of ESWT.

## PATIENTS AND METHODS

The prospective, randomized, controlled study included 42 patients (29 males, 13 females; mean age: 64.0±8.5 years; range, 47 to 80 years) with a diagnosis of stroke who applied to the Department of Physical Medicine and Rehabilitation of the Manisa Celal Bayar University Faculty of Medicine between June 2022 and August 2023. The inclusion criteria encompassed patients aged 47 to 80 years who had not experienced a stroke previously, with a minimum of six months and a maximum of 18 months since the onset of stroke, and a Modified Ashworth Scale (MAS) spasticity of  $\geq 1+$  in the biceps muscle. The exclusion criteria included cognitive problems, no passive movement limitations in the elbow joint of the plegic arm due to additional joint pathology, recent botulinum toxin or phenol injections for spasticity in the plegic upper extremity, changes in oral antispastic medication in the last three months, history of surgery on the plegic upper extremity, active infection in the treatment area, skin lesions hindering treatment and imaging, history of malignancy in the treatment area, and vascular complaints such as bleeding diathesis, pacemaker, deep vein thrombosis, phlebitis, varicose veins, and arterial disease. The study protocol was approved by the Manisa Celal Bayar University Faculty of Medicine Clinical Research Ethics Committee (date: 24.03.2022, no: E-85252386-050.04.04.04-275191). Written informed consent was obtained from all participants. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patients were divided into two groups according to the randomization diagram accessed online. The first group (n=21) received conventional physical therapy, while the second group (n=21) received rESWT in addition to conventional physical therapy.

Patients in this study received conventional physical therapy while hospitalized for four weeks. During this period, they participated in daily sessions that included passive and active range of motion exercises for the elbow joint, therapeutic stretching, strength exercises, neurophysiological exercises,

activities of daily living with an emphasis on gross and fine grip, and occupational therapy education. After the four-week hospitalization, both the treatment and control groups were instructed by physiotherapists to perform the exercises taught to their caregivers three times a day.

For the rESWT group, the BTL-5000 SWT Power device (BTL Industries, Praque-Czech Republic) with a 15-mm transmitter head was used. The patient was positioned supine, and after fixing the upper arm in 30° shoulder abduction and 180° elbow extension, the skin surface of the affected side's arm was evenly covered with a coupling agent, followed by shock treatment. For the ESWT procedure, the probe was initially placed near the spastic biceps muscle belly to start the treatment. During the session, the probe was moved to cover the distal and proximal tendons of the biceps as well as the muscle belly, ensuring comprehensive treatment of the affected area. Shock treatment, with a pressure of 2 bars, a frequency of 6 Hz, and 2,000 pulses within tolerable pain limits, was applied continuously and smoothly, completing the treatment in approximately 5 min. Patients received four sessions of treatment weekly for a total of four weeks.

The demographic information of patients included in the study was recorded during the initial examination using the case follow-up form. In both groups, assessments were performed using the MAS, Modified Tardieu Scale (MTS), Fugl-Meyer Upper Extremity Motor Assessment (FMA-UE), and Functional Independence Measure (FIM) before treatment, at the end of treatment, four weeks after treatment, and 12 weeks after treatment. Shear wave elastography measurements were also taken and were used as the primary evaluation criterion during follow-up, with MAS, MTS, FMA-UE, and FIM used as secondary evaluation criteria.

In the study, SWE was employed to measure the tissue hardness of spastic biceps muscle in patients. The measurements were conducted using the ESAOTE S.p.A Via Enrico Malen 77, 16152 Genova, Italy, MyLabX8 Exp ultrasound device (ESAOTE S.p.A., Genoa, Italy) with a linear high-frequency probe (4-15 MHz).

Patients were placed supine on the examination table with their elbows and shoulders in a neutral, comfortable position for taking measurements. Elastography measurements were taken with the elbow in a 0° flexion position (full extension) and then in a 90° flexion position. The coracoid process was connected

to a location one-third below the line by placing the probe over a point that was equally spaced between the medial and lateral epicondyles to standardize the position of measurements. The region corresponding to the center of the biceps muscle belly was identified as the region of interest. [8] To acquire SWE data, the probe was oriented longitudinally in a direction parallel to the muscle fibers. A thin layer of acoustic gel was applied to the skin during measurements, and the probe was held steady throughout the SWE acquisition.

All outcome measurements, including both ultrasonographic elastography and clinical assessments, were conducted by a physiatrist with extensive experience exceeding 10 years in musculoskeletal ultrasound. The evaluator was blinded to the treatment allocations to ensure impartiality in the assessment of outcomes. The treatment planning and random allocation of patients into the respective groups were performed by another physiatrist to maintain the integrity of the randomization process. Furthermore, all patients received conventional therapy from a single physiotherapist who was blinded to the treatment allocations.

# Statistical analysis

The sample size calculation was conducted using the G\*Power version 3.1.9.7 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). The sample size calculation was performed to assess differences in SWE measurement between the experimental and control groups. Accordingly, a total of 42 patients, with at least 21 individuals in each group, were determined to be necessary for the study, with a power of 0.70, an effect size of 0.80, and a 0.05 error margin.

Data were analyzed using the IBM SPSS version 24.0 software (IBM Corp., Armonk, NY, USA)  $Descriptive \, statistics \, were \, presented \, as \, mean \, \pm \, standard$ deviation (SD) for normally distributed variables and median (min-max) for nonnormally distributed variables. Nominal variables were evaluated with the chi-square test. The normal distribution of variables was examined visually (histograms and probability plots) and analytically (Kolmogorov-Smirnov). Differences between groups in terms of continuous variables in the study were investigated using the Mann-Whitney U test for independent groups. Within-group differences in continuous variables in the study were explored using the Wilcoxon test for dependent groups. The spearman correlation test was used for the correlation analysis of numerical

iv Turk J Phys Med Rehab

				T	TABLE 1	_							
Sociodemographic characteristics, including sex, education level, hemiplegic side, stroke etiology, age, duration of stroke, and Brunnstrom score	eristics,	includi	ing sex, educat	ion level, hen	niplegi	c side,	stroke etiology	7, age, duratio	n of st	roke, a	nd Brunnstro	m score	
		Treat	Treatment group (n=21)	:21)		Con	Control group (n=21)	11)			Total (n=42)		
	п	%	Mean±SD	Min-Max	u	%	Mean±SD	Min-Max	п	%	Mean±SD	Min-Max	Ъ
Age (year)			64.0±8.7	47-80			63.9±8.2	51-79			$64.0\pm 8.5$	47-80	0.86
Sex													0.739
Male	14	66.7			15	71.4			29	69.1			
Female	^	33.3			9	28.6			13	30.9			
Education level													0.641
Illiterate/primary school	6	42.9			^	33.3			16	38			
High school	^	33.3			10	47.6			17	40.5			
Undergraduate/graduate	5	23.8			4	19			6	21.4			
Hemiplegic side													1
Right	12	57.1			12	57.1			24	57.1			
Left	6	42.9			6	42.9			18	42.9			
Stroke etiology													0.707
Ischemic	17	81			16	76.2			33	78.6			
Hemorrhagic	4	19			2	23.8			6	21.4			
Duration of stroke (month)			$13.19\pm3.38$	6-18			$11.04\pm3.82$	6-18					0.058
Brunnstrom score			$3.14\pm0.72$	2-4			2.9±0.7	2-4					0.279
SD: Standard deviation.													

data. Intraclass correlation coefficient analysis was performed to determine the consistency of SWE evaluations. Results were considered statistically significant for p<0.05.

## **RESULTS**

The sociodemographic data of the participants are presented in Table 1. When sociodemographic data were examined, no statistically significant difference was found between the two groups (p>0.05; Table 1). In the treatment group, a significant decrease in MAS (p=0.013 and p=0.02, respectively) and MTS (p=0.046 and p=0.034, respectively) was observed in the fourth and eighth weeks compared to the initial examination. However, there was no significant change in the 16-week measurement (p>0.05). For the control group, measurements at the fourth, eighth, and 16th weeks showed no significant changes compared to the initial examination (p>0.05). There was no statistically significant difference between the treatment and control groups in terms of MAS and MTS measurements at baseline and fourth, eighth, and 16th weeks (p>0.05; Table 2).

In the treatment group, FMA-UE scores in the fourth, eighth, and 16<sup>th</sup> weeks exhibited a significant increase compared to the initial examination (p=0.015, p=0.043, and p=0.01, respectively). In the control group, FMA-UE scores at fourth and eighth weeks showed no significant change compared to the initial examination (p>0.05). However, in the control group, the FMA-UE score in the 16<sup>th</sup> week demonstrated a significant increase compared to the initial examination (p=0.046). There was no significant difference between the treatment and control groups in terms of FMA-UE scores at baseline and fourth, eighth, and 16<sup>th</sup> weeks (p>0.05; Table 3).

In the treatment group, FIM scores in the fourth, eighth, and  $16^{\rm th}$  weeks demonstrated a significant increase compared to the initial examination (p=0.022, p=0.006, and p=0.003, respectively). In the control group, FIM scores in the fourth and eighth weeks showed no significant change compared to the initial examination (p>0.05). However, in the control group, the FIM score in the  $16^{\rm th}$  week exhibited a significant increase compared to the initial examination (p=0.018). There was no significant difference between the treatment and control groups in terms of FIM scores at baseline and fourth, eighth, and  $16^{\rm th}$  weeks (p>0.05; Table 3).

For the plegic arm in 180° extension and 90° flexion, SWE measurements in the treatment group

				TITLE T						
	Within-gr	oup and betw	veen-group cor	nparisons of	changes in N	Within-group and between-group comparisons of changes in MAS and MTS by treatment	by treatment			
			MAS score				MTS	MTS-angle of spasticity	ity	
	Treatment group	roup (n=21)	Control group (n=21)	up (n=21)	Difference between groups	Treatment group (n=21)	oup (n=21)	Control group (n=21)	up (n=21)	Difference between groups
	Mean±SD	Min-Max	Mean±SD	Min-Max	d	Mean±SD	Min-Max	Mean±SD	Min-Max	р
Baseline	2.09±0.76	1-3	2.04±0.8	1-3	0.851**	34.47±16.58	9-64	$31.95\pm16.87$	10-64	0.678**
4 <sup>th</sup> week	$1.66\pm0.85$	1-3			0.335**	$32\pm 16.16$	8-64	$31.80\pm17.26$	10-64	0.99**
Within-group difference $(p)$	0.013*	13*	$0.414^{\star}$	*#		$0.046^{*}$	*9	$0.531^{*}$	<u>*</u> _	
8 <sup>th</sup> week	$1.76\pm0.62$	1-3	$1.90\pm1.04$	1-3	0.497**	$32.09\pm15.36$	9-64	$31.28\pm17.27$	10-63	0.831**
Within-group difference $(p)$	0.020*	*03	$0.317^{*}$	* _		$\boldsymbol{0.034^{\star}}$	**	$0.161^{*}$	*_	
16 <sup>th</sup> week	$1.90\pm0.76$	1-3	2±1.04	1-3	0.578**	$32.52\pm15.42$	9-64	$30.57\pm16.86$	8-61	**699.0
Within-group difference $(p)$	$0.206^{*}$	<sub>*</sub> 9(	0.782*	*2		$0.61^{*}$	*.	$0.156^{*}$	*5	
MAS: Modified Ashworth Scale, MTS: Modified Tardieu Scale; SD: Standard deviation; * Wilcoxon test; ** Mann-Whitney U test	Tardieu Scale; SD: S	tandard deviation;	* Wilcoxon test; ** I	ɗann-Whitney U	test.					

				TARLE3						
	Within-grou	p and betwe	en-group com	varisons of cl	hanges in FN	Within-group and between-group comparisons of changes in FMA-UE and FIM by treatment	M by treatmo	ent		
			FMA-UE score					FIM score		
	Treatment group	oup (n=21)	Control group (n=21)	up (n=21)	Difference between groups	Treatment group (n=21)	oup (n=21)	Control group (n=21)	up (n=21)	Difference between groups
	Mean±SD	Min-Max	Mean±SD	Min-Max	ф	Mean±SD	Min-Max	Mean±SD	Min-Max	р
Baseline	19.85±8.29	4-32	19.09±9.16	6-34	0.782**	66.33±16.01	36-92	64.19±11.22	39-83	0.597**
4 <sup>th</sup> week	$22.42\pm 8.32$	5-35	19.47±10.15	7-37	0.364**	68.52±15.16	39-93	$65\pm10.94$	39-83	0.365**
Within-group difference $(p)$	$0.015^{*}$	χ.	$0.481^{*}$	*1		$0.022^{\star}$	<b>.</b> 2,	$0.282^{*}$	, , ,	
8 <sup>th</sup> week	$21.61\pm7.97$	5-36	$19.95\pm9.58$	7-38	0.545**	$69.66 \pm 14.67$	41-94	$65.52\pm11.21$	39-85	0.302**
Within-group difference $(p)$	0.043*	*£	$0.120^{*}$	*0		₹900.0	, <b>9</b>	0.057×	*_	
16 <sup>th</sup> week	22.28±7.73	7-38	$20.28\pm 9.15$	8-38	0.597**	$71.09\pm14.03$	43-94	$66.85\pm10.91$	41-85	0.195**
Within-group difference $(p)$	$0.010^{*}$	*0	$0.046^{\star}$	*9		0.003∗	13*	$0.018^*$	*8	
FMA-UE: Fulg-Meyer Upper Extremity Assessment; FIM: Functional Independence Measures; SD: Standard deviation; * Wilcoxon test; ** Mann-Whitney U test	nent; FIM: Functional	Independence M	easures; SD: Standar	d deviation; * Wil	coxon test; ** Maı	nn-Whitney U test.				

				TABLE 4						
	With	in-group and	between-gro	up comparisc	Within-group and between-group comparisons of changes in SWE by treatment	in SWE by tr	eatment			
		SWE 180	SWE 180 degree extension (m/s)	(s/m) uo			SWE 9	SWE 90 degree flexion (m/s)	(s/m) u	
	Treatment group (n=21)	roup (n=21)	Control group (n=21)	oup (n=21)	Difference between groups	Treatment group (n=21)	roup (n=21)	Control group (n=21)	oup (n=21)	Difference between groups
	Mean±SD	Min-Max	Mean±SD	Min-Max	Ъ	Mean±SD	Min-Max	Mean±SD	Min-Max	Ъ
Baseline	3.97±0.77	3.03-5.8	4.03±0.64	3.24-5.34	0.571**	2.25±0.5	1.4-2.98	2.35±0.47	1.49-2.96	0.505**
4 <sup>th</sup> week	$3.46\pm0.39$	3.01-4.29	$3.91\pm0.57$	3.01-5.13	$0.012^{**}$	$1.94\pm0.46$	1.27-2.86	$2.32\pm0.42$	1.59-2.98	0.017**
Within-group difference $(p)$	0.0	0.003*	0.205*	)5*		$0.040^{\star}$	<b>40</b> *	$0.414^{*}$	*47	
8 <sup>th</sup> week	3.57±0.47 3.06-4.70	3.06-4.70	$3.97\pm0.58$	3.03-5.26	$0.026^{**}$	$1.99\pm0.43$	1.38-2.61	$2.31\pm0.43$	1.53-2.92	0.018**
Within-group difference $(p)$	0.0	0.005*	$0.130^{*}$	*0*		0.013*	13*	0.073*	73*	
16 <sup>th</sup> week	$3.78\pm0.61$ $3.11-5.32$	3.11-5.32	4±0.61	3.08-5.25	0.285**	$2.15\pm0.46$	1.44-2.97	2.34±0.44 1.54-2.93	1.54-2.93	0.232**
Within-group difference $(p)$	0.11	0.118**	0.113**	3**		0.170*	*02	$0.421^{*}$	21*	
SWE: Shear wave elastography; SD: Standard deviation; * Wilcoxon test; **	viation; * Wilcoxon t	est; ** Mann-Whitney U test.	ney U test.							

at the fourth and eighth weeks demonstrated a significant decrease compared to the initial examination (p<0.05), but no significant change was observed at the 16<sup>th</sup> week (p>0.05). In the control group, SWE measurements in the fourth, eighth, and 16<sup>th</sup> weeks showed no significant change (p>0.05). Shear wave elastography measurements in the fourth and eighth weeks in the treatment group were statistically significantly lower than the control group (p<0.05; Table 4).

Correlation analysis was performed to examine the relationship between spasticity scores determined by MAS and SWE measurement values obtained at 90° flexion and 180° extension. For evaluations at baseline and fourth, eighth, and 16<sup>th</sup> weeks, a positively and moderately high statistically significant correlation was observed between MAS scores and SWE measurement values (r=0.826, r=0.634, r=0.711, and r=0.674, respectively; p<0.01). The intraclass correlation coefficient for SWE evaluations was found to be 0.939 (p<0.001).

### DISCUSSION

When we assessed the severity of spasticity in the reference biceps muscle using both clinical methods and ultrasonographic elastography, we observed a significant improvement immediately after and in the short term following ESWT in the treated group, which diminished in the long term. These changes were statistically significant in SWE measurements between the groups. The significant difference observed in SWE measurements underlines the improved sensitivity and reliability of this method compared to conventional clinical assessments.

The findings suggest that SWE is a more reliable tool for the objective assessment of spasticity, highlighting the need for a more detailed examination of the long-term effects of ESWT. Reviewing existing studies in the literature evaluating the effectiveness of ESWT in spasticity treatment, similar efficacy has been observed immediately after treatment and within 24 h in studies comparable to ours. However, in many studies, the effectiveness persists in the first month after treatment, while some studies report that the observed efficacy in the acute phase diminishes in the first month. [8-21]

The number of studies involving long-term follow-ups is quite limited, and these studies have yielded different results. Our study is one of the few that includes long-term follow-ups. Taheri et al.'s<sup>[17]</sup> and

Li et al.'s<sup>[22]</sup> studies, which found similar results to our study at the end of treatment and in the fourth week, obtained different results in longer-term follow-ups. Li et al.<sup>[22]</sup> adopted an approach similar to our study in a single-blind randomized controlled trial. They applied conventional rehabilitation to all patients and selected the wrist flexor muscles as the spastic muscle group. The treatment dose they applied was 1,500 impulses at a frequency of 5 Hz and a pressure of 3.5 bars. In this study, statistically significant improvement was reported to continue up to eight weeks in the group receiving a single-session treatment and up to 16 weeks in the group receiving three sessions.

The presence of studies with different results in longer-term follow-ups suggests that the effects of ESWT on spasticity may change over time and are dependent on various factors. Factors such as the selected spastic muscle groups, the duration and severity of patients' strokes, the number of sessions applied, the intervals between sessions, variations in ESWT doses, and differences in evaluation methods may lead to different outcomes in the medium and long term. Therefore, future studies should examine these factors in more detail.

The lack of a standardized number of sessions and dosage for ESWT in spasticity treatment indicates a general inconsistency in the literature. It is important to note that a meta-analysis has provided recommendations regarding dosage and session parameters.<sup>[7]</sup> According to this metaanalysis, the recommended pressure level for ESWT applications is between 1.0 and 2.0 bars, and the frequency is between 4 and 8 Hz. Additionally, it is suggested that one session is insufficient, and a total of three to four sessions should be performed with a one-week interval between sessions. In parallel with these recommendations, the ESWT protocol applied to patients in our study was planned in accordance with the specified standards. The patients received a treatment protocol with a pressure of 2 bars, a frequency of 6 Hz, and 2,000 impulses. These sessions were organized weekly for four weeks, totaling four sessions. At the same time, we focused on the direct application of ESWT to both the muscle belly and the myotendinous junction of the spastic muscle during treatment to increase the effectiveness of ESWT, as recommended in the literature. This approach aimed to comprehensively evaluate the effect of ESWT on the spastic muscle. The standardized protocol in our study contributes to the comparability of the study results with other

viii Turk J Phys Med Rehab

similar studies and provides a general framework for the effectiveness of ESWT in spasticity treatment.

According to the data in our study, FIM scores and FMA-UE scores showed a significant improvement in all measurements treatment compared to before treatment in the treatment group. However, in the control group, this improvement was only observed in the last measurement after treatment. The significant improvement in both groups in the last measurement emphasizes the importance of the continuation of the treatment process, highlighting the long-term effects of conventional rehabilitation. The faster and more pronounced improvement in daily life activities and motor functions in the group receiving ESWT treatment, in addition to conventional rehabilitation, suggests that ESWT may be an effective option, particularly in the early stages of spasticity management, and more significant results can be obtained when used in conjunction with long-term rehabilitation. When examining studies in the literature, we observed similar results to studies using the Fulg-Meyer Assessment Scale as an assessment method. [11,21,23-26] However, we did not come across a study evaluating the FIM.

In our study, the use of SWE as a method for the objective assessment of spasticity allowed a more detailed examination than traditional physical examination methods and primitive elastography methods. This approach, which is an important feature of our study, provided a more comprehensive evaluation of the effectiveness of ESWT applied for the purpose of spasticity treatment. In the literature, clinical methods such as MAS and MTS are generally preferred to evaluate the effects of ESWT on spastic muscles.

A study evaluated the effects of ESWT applications on the spasticity of ankle plantar flexor muscles in post-stroke patients. [27] In this study, in addition to traditional clinical methods, strain elastography was used. Similar to our study, ESWT was effective in the short term, but the treatment effects decreased and were not permanent in the long term. However, in our study, the results obtained using SWE showed that spasticity was evaluated more sensitively and reliably compared to traditional clinical methods. Conversely, in the study using strain elastography, no similar significant differences were found. [27]

In strain elastography, the transducer applies a force by repetitively applying manual pressure,

and the displacement (strain) is computed from the tissues' return velocities over time. However, because the amount of applied force is unknown, real quantitative measurements cannot be obtained from this method. Shear wave elastography, on the other hand, uses a concentrated ultrasonic pulse produced by the transducer to apply vibrations to the tissues. Transverse waves, also known as shear waves, are produced by this build-up of energy within the tissues and are perpendicular to the pushing pulse. The Doppler frequency modulation of ultrasonic waves that are concurrently broadcast can be used to calculate shear wave velocities. In this context, SWE stands out as a method with objective characteristics and reproducible results in the evaluation of spastic muscles.[28]

In cross-sectional designed studies, SWE has been selected as a preferred method in studies correlating with clinical methods such as MAS and MTS, and it has been concluded that SWE is an effective method for the quantitative evaluation of spasticity.[8,29-33] In a study that did not include a control group, patients were evaluated with SWE before and after treatment to assess the effectiveness of conventional rehabilitation.[34] This study, which showed a correlation with measurements made with MAS, contributed to the use of SWE as a quantitative assessment tool in monitoring spasticity treatment. In another study, seven patients with spasticity in the biceps after stroke were treated with botulinum toxin type A. Shear wave elastography was used to quantitatively evaluate the effectiveness of botulinum toxin injections in spasticity treatment.[35] The findings obtained using SWE in our study allowed a more objective and accurate evaluation of the effects of ESWT on spasticity. It can be said that SWE is a superior and sensitive assessment tool compared to other clinical methods used in the evaluation of spasticity. This indicates that the use of SWE in future studies will be important for optimizing ESWT treatment protocols and better understanding its long-term effects.

One limitation of this study was the sample size calculation, which used a power of 0.70. Although this aligns with similar studies, it is generally recommended that the power be 0.80 or greater to reduce the likelihood of type 2 errors. Future research should consider a larger sample size to achieve higher power and ensure more robust results. Another limitation was that the experimental group received additional therapy that was not given to the control group.

Incorporating a sham treatment group could help prevent such biases. Future studies should consider a sham group to ensure more accurate comparisons.

In conclusion, this study highlighted the short-term efficacy of rESWT as an adjunct to conventional rehabilitation in reducing spasticity in post-stroke patients with biceps muscle involvement. While significant improvements were observed immediately after treatment and at the one-month follow-up, these effects diminished by the three-month follow-up. In addition, the results highlight the correlation between SWE measurements and traditional clinical assessment methods, suggesting the potential of SWE to improve the objective assessment and monitoring of spasticity treatment outcomes.

**Data Sharing Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

**Author Contributions:** Idea/concept, design, control/supervision, data collection and/or processing, critical review, references and fundings, materials: I.C.O., C.T.; Analysis and/or interpretation, literature review, writing the article: I.C.O.

**Conflict of Interest:** The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

**Funding:** The authors received no financial support for the research and/or authorship of this article.

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X Turk J Phys Med Rehab

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