

Radial Extracorporeal Shock Wave Therapy for Triceps Surae Spasticity in People With Multiple Sclerosis: A Pilot Study

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ABSTRACT

BACKGROUND: Spasticity represents a major symptom of people with multiple sclerosis (MS), frequently causing disability, pain, and abnormal postures. The aim of this study is the evaluation of safety and efficacy of radial extracorporeal shock wave therapy (RESWT) for triceps surae muscle spastic hypertonia in people with MS.

METHODS: Two centers recruited people 18 years or older with MS and triceps surae muscle hypertonia. People were excluded if they had other neurological conditions; had used anticoagulants; had intrathecal baclofen, botulinum toxin, and/or physiotherapy within the past 8 months; or had oral antispasmodics therapy modification in the past 4 weeks. The participants underwent triceps surae RESWT once a week for 4 weeks. Participants were scored on the Modified Ashworth Scale (MAS), the Numerical Rating Scale for spasticity (NRS-Sp), the Medical Research Council (MRC) scale, the Timed Up and Go (TUG) test, and the Timed 25-Foot Walk (T25-FW) test before RESWT (T₀) and immediately after RESWT (T₁). Self-perceived effect was evaluated via the Global Perceived Effect (GPE) at T₁.

RESULTS: Twenty-six people with MS were included (10 women and 16 men; mean age $\pm$ SD, 52.46 ± 8.39 years; mean Expanded Disability Status Scale score $\pm$ SD, 5.44 ± 1.34 ; mean disease duration $\pm$ SD, 14.88 ± 10.83 years), and 36 triceps surae were treated. MAS and NRS-Sp scores decreased at T₁, whereas TUG, T25-FW, and MRC scores were comparable over time. Via the GPE, 73% of participants reported a self-perceived positive effect of RESWT on spasticity.

CONCLUSIONS: RESWT may be efficacious and safe for treating spasticity in people with MS and does not adversely affect gait, strength, or dynamic balance. Further long-term studies are needed to evaluate the possibility of using RESWT as a treatment for spasticity in people with MS.

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Spasticity affects up to 80% of people with multiple sclerosis (MS), frequently provoking disability, pain, or abnormal posture,¹ making its treatment a matter of paramount importance. Several pharmacological and nonpharmacological treatments for MS-related spasticity are currently available, including oral antispasmodics, intrathecal baclofen, oromucosal spray nabiximols, intramuscular botulinum toxin injections, and physiotherapy.² In a recent consensus paper,² the guideline panel gave only a weak recommendation for oral antispasmodics for MS-related spasticity and the data showed that baclofen, gabapentin, or tizanidine administration might expose people with MS to adverse effects, such as muscle weakness, nausea, and somnolence.² Conversely, intrathecal baclofen, cannabinoids, and botulinum toxin received strong recommendations, although their use is expensive.³

Of nonpharmacological treatments, physiotherapy (in particular, supervised outpatient training) is currently considered safe and effective in reducing spasticity in people with MS,^{2,4} and although there is a lack of randomized controlled trials about physiotherapy,^{2,4} it is used in routine clinical practice.²

Recently, another nonpharmacological therapy has been proposed. After being used for orthopedic conditions such as tendinopathies,⁵ radial extracorporeal shock wave therapy (RESWT) has been studied in people with spasticity and neurological disorders,^{6,7} including stroke⁶⁻¹⁰ and MS.¹¹⁻¹³ At the time of our research, no studies directly investigated the effect of RESWT on MS-related focal spasticity without possible confounding factors, such as botulinum toxin administration; thus, we present data from a pilot study by our own group evaluating RESWT on ankle plantar flexor spasticity, walking, and balance in people with MS.

METHODS

This is an uncontrolled, pre-post, multicenter clinical trial involving 2 Italian centers: C.R.R.F. Mons. Luigi Novarese in Moncrivello and Dipartimento di Neuroscienze, Riabilitazione, Oftalmologia, Genetica e Scienze Materno-Infantili at the University of Genoa.

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Recruited participants had an MS diagnosis (revised McDonald criteria¹⁴), were 18 years or older, had muscle hypertonia as defined by the Modified Ashworth Scale (MAS; score ≥ 1 of triceps surae; ie, gastrocnemius lateralis, gastrocnemius medialis, and soleus), and had sufficient cognitive function to give informed consent and understand instructions (Mini-Mental State Examination score ≥ 24 of 30). People with MS were excluded if they had other neurological conditions, if they were using anti-coagulants, if they were being treated with intrathecal baclofen, if they had botulinum toxin and/or physiotherapy within the past 8 months, and if they had been on oral antispasmodics therapy in the past 4 weeks.

The study was conducted in accordance with the Declaration of Helsinki and approved by the local ethical committee, Comitato Etico Interaziendale A.O. SS. Antonio e Biagio e Cesare Arrigo di Alessandria (0019689; September 24, 2021). All study enrollees provided written informed consent.

All participants underwent 4 sessions of RESWT (3000 shots at 4 Hz and 1.5 bar) lasting 15 minutes, once per week, which were delivered by the same clinician (M.B.). They were evaluated at baseline (To: before the first RESWT session) and after 4 sessions of RESWT (T1: immediately after the fourth session) with MAS¹⁵ score of the triceps surae as the primary outcome of the study and determined by the same clinician (R.D.G.) for each participant. Scores on the Numerical Rating Scale for spasticity (NRS-Sp),¹⁶ the Medical Research Council (MRC) scale for strength of triceps surae, the Timed Up and Go test (TUG),¹⁷ and the Timed 25-Foot Walk test (T25-FW)¹⁸ were secondary outcomes.

In addition, possible adverse effects were registered after every RESWT session by the operator using an ad hoc questionnaire investigating the presence of superficial bruises, tingling, erythema, and/or pain (yes/no).

At T1, the Global Perceived Effect (GPE)¹⁹ scale was used to assess subjective effect perception after treatment (1, very much deteriorated, to 7, very much improved).

Measures

The MAS¹⁵ is a manual test evaluating muscle tone on the basis of the degree of resistance to passive movement of body segments as perceived by the examiner (0, no increase in muscle tone; 1, slight increase in muscle tone with a catch and release or minimal resistance at the end of the range of motion; 1+, slight increase in muscle tone manifested as a catch followed by minimal resistance through the remainder [less than half] of the range of motion; 2, marked increase in muscle tone throughout most of the range of motion [affected part is still easily moved]; 3, considerable increase in muscle tone with difficult passive movement; 4, the affected part is rigid in flexion or extension. The number 1.5 was used for the numerical analysis for the 1+ degree modification.

The NRS-Sp¹⁶ is an assessment of individual-perceived spasticity with a range of 0 (none) to 10 (severe).

The MRC²⁰ is an objective, validated scale commonly used for the evaluation of muscle strength in patients with orthopedic and neurologic conditions (grade 0, no visible contraction; grade 1, visible contraction without movement of the limb; grade 2, movement of the limb but not against gravity; grade 3, movement

PRACTICE POINTS



An improvement of triceps surae spasticity in 26 people with multiple sclerosis was observed after 4 sessions of radial extracorporeal shock wave therapy (RESWT) with 3000 shots at 4 Hz and 1.5 bar.

In the treated participants, muscle strength, walking speed, and dynamic balance remained unchanged after RESWT. In addition, there were no adverse effects. ■

against gravity over almost the full range; grade 4, movement against gravity and moderate resistance; grade 5, normal strength).

The TUG¹⁷ is a dynamic balance measure requiring the participant to stand up from a chair, walk 3 m, turn around, walk back to the seat, and sit down again. The score is the time recorded from the chair lift to the resit.

The T25-FW^{18,21} objectively assesses walking disability on the basis of the walking speed that the patient requires to ambulate a clearly marked 25 ft (7.62 m) as quickly and safely as possible. The score registered is the average of the time of 2 trials.

The GPE¹⁹ is a scale of subjective effect perception after any treatment (1, very much deteriorated, to 7, very much improved).

Statistical Analysis

Due to the nonnormal distribution of the parameters, nonparametric tests were used. Wilcoxon signed rank test was used for the comparison of MAS, MRC, TUG, T25-FW, and NRS-Sp scores at To vs T1. In addition, Δ values for TUG and T25-FW were computed, subtracting the To value from the T1 value. Participants were divided into 3 groups according to MS type—relapsing-remitting MS (RRMS), primary progressive MS (PPMS), and secondary progressive MS (SPMS)—and the scores were compared with the Kruskal-Wallis test. Furthermore, a χ^2 test was used to compare the proportion of distribution of MAS at To and T1.

Spearman correlation analysis was performed to assess the possible correlation among the Expanded Disability Status Scale (EDSS), MAS, MRC, TUG, T25-FW, NRS-Sp, Δ TUG, and Δ T25-FW. In particular, the possible correlation between the EDSS and the other cited parameters was investigated. Effect size measures were calculated as appropriate.

RESULTS

There were 26 participants: 10 women and 16 men. The clinical and demographic characteristics of the study population are shown in **TABLE 1**. Seven participants walked without assistive devices, 7 walked with a single cane, 1 used 2 canes for walking, and 11 ambulated with a walker. None of the participants changed their assistive device at T1 evaluation. All the participants completed the study, and no treatment sessions were missed. In addition, no adverse effects were registered during RESWT.

The outcome measures are shown in **TABLE 2**. A significant reduction in MAS and NRS-Sp scores was found at T1. MAS value distribution at To and T1 (**FIGURE 1**) did not change significantly ($\chi^2 = 10.982$; $df = 16$; $P = .811$). No significant differences over time were found for TUG, T25-FW, or MRC scores. In addition, there were no differences among participants with RRMS, SPMS, or PPMS in MAS, MRC, TUG, T25-FW, NRS-Sp, or GPE scores from To to T1.

At T1, GPE had a mean score of 5.12 ± 1.05 , with 73% of participants reporting a self-perceived positive RESWT effect on triceps surae spasticity (**FIGURE 2**).

No significant correlations were observed among MAS, MRC, TUG, T25-FW, and NRS-Sp. As expected, EDSS was strongly related with T25-FW at To ($P = .0001$; $r = 0.655$), T25-FW at T1 ($P = .0002$; $r = 0.652$), TUG at To ($P = .0001$; $r = 0.774$), and TUG at T1 ($P = .0008$; $r = 0.626$). In contrast, EDSS was not linked to Δ T25-FW ($P = .67$; $r = 0.090$), Δ TUG ($P = .236$; $r = 0.246$), and GPE ($P = .833$; $r = 0.043$).

DISCUSSION

Spasticity is a complex symptom and major cause of pain and disability in people with MS,^{1,2} and its management is still a challenge.^{1,2}

Findings from the present uncontrolled, pre-post, multicenter clinical trial suggest that RESWT was efficacious in reducing focal spasticity of the triceps surae in people with MS and that the protocol applied had no adverse effects. After 4 weeks of treatment, MAS scores were reduced significantly, with a parallel reduction of NRS-Sp score and a high GPE score at T1. Thus, after RESWT,

TABLE 1. Participant Clinical and Demographic Characteristics (N=26)

Women	10 (38.5%)
Men	16 (61.5%)
Age, years ^a	52.46 ± 8.39
EDSS score ^a	5.44 ± 1.34
Number of lower limbs treated	36
RRMS	9 (34.6%)
SPMS	11 (42.3%)
PPMS	6 (23.1%)
Antispasmodic therapy	
None	23 (88.5%)
Oral baclofen	2 (7.7%)
Botulinum toxin	1 (3.8%)

EDSS, Expanded Disability Status Scale; PPMS, primary progressive multiple sclerosis; RRMS, relapsing-remitting multiple sclerosis; SPMS, secondary progressive multiple sclerosis.
^aData presented as mean ± SD.

both an objective decrease and subjective decrease of spasticity were detected.

At the time of writing, 2 reports studying RESWT in people with MS are available. Marinelli and colleagues³¹ investigated the use of RESWT on ankle flexor pain and spasticity in people with MS, finding a beneficial effect on the 2 parameters but not on spinal excitability measured with H-reflex. The primary outcome was represented by a decrease of pain, whereas spasticity reduction was a secondary outcome. MAS was reevaluated 1 week after the end of the RESWT, or 5 weeks after the start of treatment. This was in line with our study in which a significant MAS score reduction was observed at T1.

Marinero and colleagues³² assessed the efficacy of RESWT in combination with botulinum toxin injection, revealing a synergic effect that boosted botulinum toxin injection efficacy in people with MS. However, RESWT was applied 120 days after botulinum toxin administration. In this case, the use of RESWT augmented the efficacy of the chemodenervation procedure, although the beneficial effects were not maintained at 1 and 3 months after the RESWT.

In contrast to the study by Marinero et al,³² the number of shots administered in our study was far greater, as we used RESWT to directly modify MS-related spasticity and not to enhance the effect of botulinum toxin. The number of shots delivered in other reports applying RESWT for spasticity in MS³¹ and in other neurologic conditions^{9,10,22} is always above 1500.

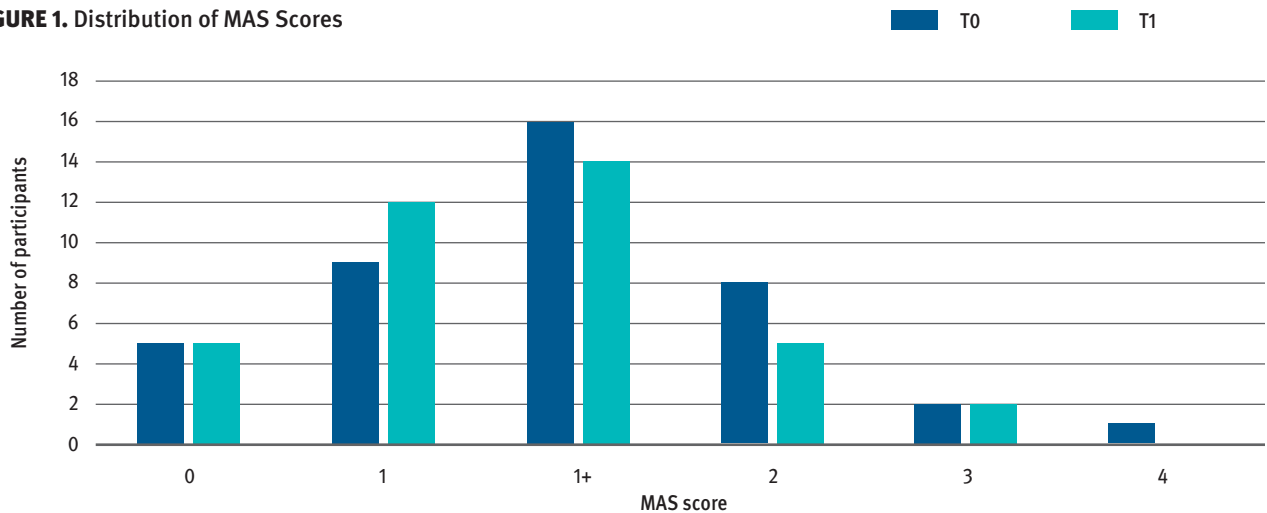
It is thought that RESWT might exert a direct mechanical action of lysis on fibrosis and impaired extensibility of muscular fibers (intrinsic hypertonia),²³ an alteration consistently encountered in spastic muscles of patients with upper motor neuron syndrome.²³

We also focused on the assessment of functional activity measures for people with MS, such as the TUG and T25-FW, in association with the

TABLE 2. Participant Clinical Characteristics at T0 and T1

	T0, mean (SD)	T1, mean (SD)	P ^a	Effect size ^b
MAS score	1.64 (0.64)	1.25 (0.70)	.008	−0.441
NRS-Sp score	4.44 (4.25)	2.61 (± 3.1)	.020	−0.386
MRC score	4.50 (0.88)	4.69 (0.79)	.059	−0.310
TUG, s	20.48 (14.51)	18.84 (12.18)	.135	−0.290
T25-FW, s	13.39 (8.05)	12.43 (7.15)	.166	−0.271
GPE score	NA	5.12 (1.05)	NA	NA
Δ TUG, s	−1.64 (7.53)		NA	NA
Δ T25-FW, s	−0.96 (4.29)		NA	NA

GPE, Global Perceived Effect scale; MAS, Modified Ashworth Scale; MRC, Medical Research Council scale; NA, not applicable; NRS-Sp, Numerical Rating Scale for spasticity; T0, baseline; T1, after radial extracorporeal shock wave therapy; T25-FW, Timed 25-Foot Walk; TUG, Timed Up and Go.
^aSignificance was set at $P < .05$.
^b r coefficient for Wilcoxon test.

FIGURE 1. Distribution of MAS Scores

MAS, Modified Ashworth Scale; T0, baseline; T1, after radial extracorporeal shock wave therapy.

triceps surae MRC to evaluate strength, to study whether RESWT might alter these parameters. In fact, when considering the pharmacological therapeutic options, temporary focal muscle weakness after botulinum toxin injection or dizziness, somnolence, and generalized weakness after antispasmodic drugs administration might be present in people with MS.²

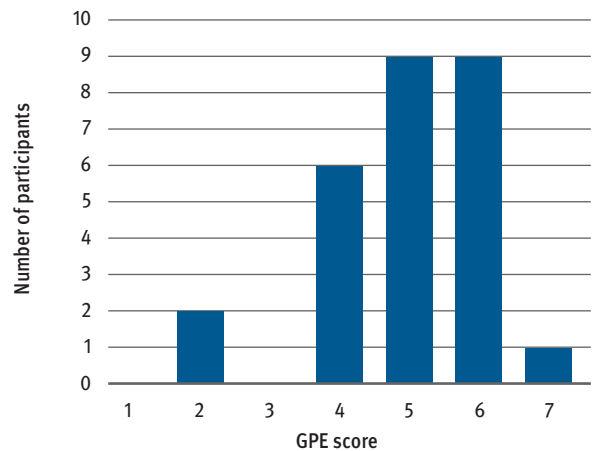
Our study results, however, did not find that RESWT influenced gait, balance, and/or muscle strength. In particular, MRC values did not decrease after treatment and TUG and T25-FW scores did not vary significantly after RESWT. This might further confirm the absence of adverse effects of RESWT when treating MS-related focal triceps surae spasticity.

At the time of this study, only Marinelli et al¹¹ documented that walking capacity remained unaffected after the reduction of focal spasticity with RESWT; the measure used was the 10-Meter Walk Test.

The T25-FW²¹ and TUG²⁴ are validated instruments for the evaluation of gait and functional mobility and dynamic balance in people with MS and are linked to EDSS and disability.²¹ In our study, the TUG and T25-FW were also strongly related to EDSS, confirming the association.^{21,25} In addition, in order to avoid any synergic or confounding action, our study included people with MS who had not changed their antispasmodic dosage in the past 4 weeks and who had not undergone botulinum toxin injection and/or physiotherapy in the past 8 months.

The majority of the people with MS in our study experienced mild focal spasticity of triceps surae, which might explain why both the TUG and T25-FW did not change over time. Another reason explaining the results might be the small sample of the study, which did not permit documenting a significant reduction of these parameters.

In addition, EDSS was related to neither triceps surae MAS at T0 or T1 nor to the Δ TUG, Δ T25-FW, and GPE. The lack of correlation between EDSS and triceps surae MAS was expected, as EDSS involves the evaluation of more than a single muscle focal spasticity. The Δ TUG and Δ T25-FW measure the change of TUG and T25-FW values between the 2 evaluations (which was not significant),

FIGURE 2. Distribution of GPE Scores at T1

GPE, Global Perceived Effect scale; T1, after radial extracorporeal shock wave therapy.

and the GPE is the individual's perceived effect of RESWT.

The opportunity to ease spasticity with RESWT in people with MS appears to be promising. However, some questions need to be answered. Above all, who among people with MS might be more easily targeted for RESWT treatment? Might RESWT be more efficacious in people with MS with mild spasticity? However, we could not conduct a valid and reliable statistical analysis comparing the 3 forms of MS due to the low number of participants and because only 3 had severe spasticity, although all responded to RESWT.

Two additional questions are whether RESWT is a first-line or adjunctive therapy and how RESWT might be integrated into the current standard of care for spasticity treatment. Our study protocol did not have any adverse effects, possibly suggesting a wider use of RESWT in the treatment of triceps surae focal spasticity. The lack of studies regarding the utilization of RESWT for treating MS-related spasticity does not allow us to exclude the possibility of utilizing this technique as an adjunctive therapy, as

demonstrated by findings from the study by Marinaro et al.

Some limitations need to be discussed. Due to the short term of this study, we do not know the duration of RESWT effect on spasticity, although the absence of adverse effects suggests a potential extension of the treatment beyond the 4 weeks in this preliminary study.

We also had a small number of participants, which might have caused the lack of significant correlations between the parameters, reducing the possibility of fully understanding the relationship between RESWT administration and the MAS, TUG, and T25-FW scores, as discussed above.

Finally, although this is a pilot study with the aim of demonstrating the efficacy of RESWT for triceps surae spasticity treatment in people with MS, the absence of a control group is also a limitation.

CONCLUSIONS

Our findings suggest that RESWT may be valid and safe for the treatment of MS-related focal spasticity, have a low cost, and have the potential to be highly repeatable. In Italy, another advantage of RESWT is the possibility of delivery by physiotherapists and occupational therapists instead of physicians only. Ancillary health care providers could be trained to administer treatment in the clinical setting and increase accessibility to RESWT.

If the results of this study are confirmed, the use of RESWT in clinical practice might improve the quality of life of people with MS and spasticity. More studies are needed to evaluate the appropriate interval between sessions, number of sessions, and the effect duration on a larger study population. ■

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