

rESWT in the Treatment of Spasticity in Cerebral Palsy: Randomized, Placebo-Controlled Clinical Trial

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Device and producing company:

Swiss Dolor Clast, EMS-Switzerland

Introduction:

Spasticity is a disorder of excess muscle tone associated with central nervous system disease. Cerebral Palsy (CP) is a central nervous system deficit resulting from a nonprogressive lesion in the developing brain. Although the brain lesions are static, the movement disorders that arise are not and they are characterized by atypical muscle tone, posture and movement. Spastic motor type is the most common form of CP and its conventional therapeutic management may include splinting/casting, passive stretching, facilitation of posture and movement, spasticity-reducing medication, botulinum toxin and surgery. ESWT reduces hypertonia of the wrist and finger muscles in patients affected by stroke (Manganotti 2005). The aim of this study was to evaluate the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in patients with cerebral palsy.

Methods:

This study is a randomized, placebo-controlled clinical trial that included 15 patients with spastic cerebral palsy; 12 men and 3 women, aged 10-46 years (mean age, 31). The 15 patients presented 40 spastic muscles (6 biceps brachii, 6 wrist flexors, 5 hip adductors, 10 gastrocnemius, 10 soleus and 3 hamstrings). The 40 spastic muscles were divided in three groups using a computerized random-number generator. Group I (14 muscles) received rESWT in spastic muscle. Group II (13 muscles) received rESWT in spastic muscle + rESWT in antagonist muscle. Group III (13 muscles) received placebo via application of a sham rESWT with sound in spastic muscle. Device used was the Swiss Dolor Clast (EMS, Switzerland). The patients were treated in 3 sessions at intervals of one week. Number of impulses was 2000 in each spastic muscle (4000 in Group II). Energy flux density was 0.10mJ/mm² (2 bar). Spasticity was evaluated by the Ashworth Scale from 0 to 4 (0: no spasticity to 4: severe spasticity) on the upper extremity muscles. Spasticity was evaluated with a goniometer (passive elongation) on lower extremity muscles. Outcomes were assessed by a blinded evaluator. Evaluation was performed immediately before treatment and at one and two months after treatment. The non-parametric Mann-Whitney U test for independent samples was used for statistical analyses.

Results:

There were no significant differences between Group I (rESWT in spastic muscle) and Group II (rESWT in spastic muscle + rESWT in antagonist muscle). However, with regard to the spastic muscles from upper limbs there were significant differences ($p=0.05$) between Group I (rESWT) and Group III (placebo). With regard to the spastic muscles of lower limbs there were significant differences ($p=0.044$) between Group I (rESWT) and Group III (placebo) as well as significant differences ($p=0.043$) between Group II (rESWT in spastic muscle + rESWT in antagonist muscle) and Group III (placebo). Observed side effects were 3 small superficial hematomas, 3 petechiae and 3 patients expressed light pain during the therapy. All side effects were tolerated by all the patients and disappeared after 1-7 days. All the patients finished the study. At the end of follow-up, all the patients were asked to assess if they would repeat the experience and all of them answered affirmatively.

Discussion:

The study presents interesting insights on the usefulness of rESWT in treating patients with cerebral palsy to reduce spastic muscle tone. The mechanism of shock wave therapy on spastic muscles is still unknown. Basic research & larger randomized controlled studies are necessary to support the results of this clinical trial.

Conclusion:

rESWT is more effective than placebo in decreasing spasticity of patients with cerebral palsy. Positive outcomes are maintained at least 2 months after treatment.