

Radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in cerebral palsy: A randomized, placebo-controlled clinical trial

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Abstract. *Aim:* 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: Fifteen patients with spastic cerebral palsy, 12 men and 3 women, aged 10–46 years (mean age 31). The 15 patients presented 40 spastic muscles that were divided in three groups using a computerized random-number generator. The first group, received rESWT in spastic muscle. The second group received rESWT in spastic muscle + rESWT in antagonist muscle. The third group received placebo. Range of motion and Ashworth Scale were performed. This study is a randomized, placebo-controlled clinical trial. The patients were treated in 3 sessions at intervals of one week.

Results: There are significant differences between groups treated with rESWT and group placebo. A significant decrease in the Ashworth Scale, an increase in the range of motion, were observed in all patients that were treated with rESWT. Positive results were maintained for at least 2 months after treatment.

Interpretation: The treatment with rESWT is more effective than placebo in decreasing spasticity of patients with CP.

Keywords: Cerebral palsy, spasticity, extracorporeal shock wave therapy, hypertonia, muscle tone

1. Introduction

Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, perception, cognition, communication, and behavior, by epilepsy, and by secondary musculoskeletal problems [1]. CP affects between 1.5 and 2.5 per 1000 live births and is thought to be the most common cause of severe physical disability in childhood [2,3]. The

spastic motor type is the most common form of CP [4]. Spasticity is a motor disorder characterized by a velocity dependent increase in tonic stretch reflexes (muscular tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex [5]. The sustained contraction of the spastic muscle groups, will result in permanent contractures and skeletal deformities, that cause the limitation of patient activity [6]. Therefore, treatment of spasticity plays an important role in the management of patients with CP. Conventional treatment of spasticity may include passive stretching [7,8], serial plastering [9,10], splints [11,12], pharmacologic treatment [13–16], and botulinum toxin [17–21]. Despite all the existing treatments, we believe that shock wave therapy, being a non-invasive therapy may be an interesting alternative in the treatment of spasticity.

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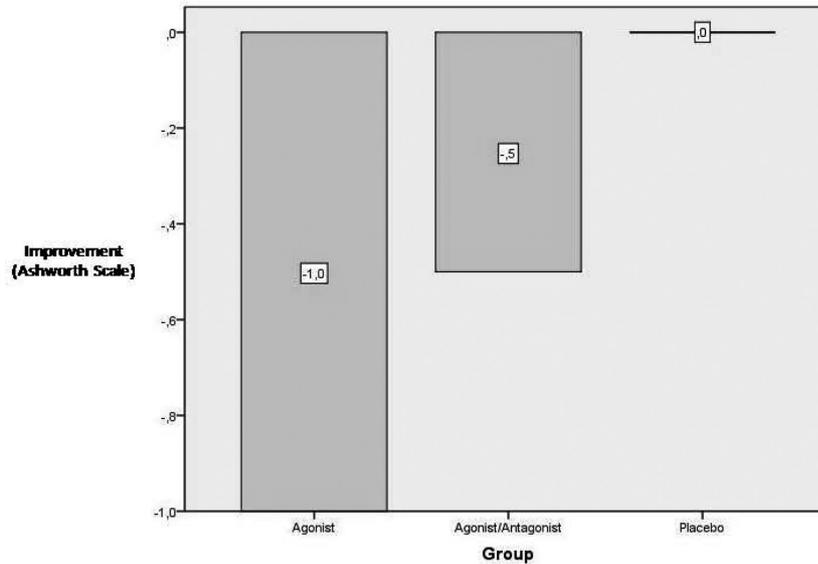


Fig. 1. Upper limb muscles. Median improvement 2 months receiving treatment. There are significant differences between group agonist and group placebo.

Shock waves are a sequence of acoustic pulse, with a high peak pressure (100 MPa), and a short life cycle (10 ms). The therapeutic effect of radial shock waves occurs a few centimeters deep to the skin surface (0 to 3.5 cm) [22]. Different studies have demonstrated the efficacy of shock waves in treating pathologies of the musculoskeletal system such as chronic tendinopathies or hypertrophic pseudoarthrosis [23–32]. Two recent studies have also demonstrated the effectiveness of shock waves in the treatment of spasticity. In the first of these studies, hypertonia reduction of the wrist and fingers muscles was observed, in patients affected by stroke [33]; in the second, a significant long-lasting reduction in hypertonia in the plantar flexors in children with CP was reported [34]. These studies suggest that spasticity can be reduced after application of shock waves. In April 2008, in the absence of literature in the field of CP we conducted an evaluation with three patients of ASPACE Barcelona, to which we applied shock waves in the muscle groups that were more spastic, mainly antigravity muscles, biceps brachii in the upper limbs, and in the lower limbs, sural triceps. The clinical results were a reduction of spasticity immediately after application and improvement of extensibility, results were maintained for a month which is the time of the first contact with this technique. After presenting these data at the world shock wave congress held in Monaco in June of 2008 and see the great impact it has caused, we decided to start this study in October 2008. We aim to evaluate in a randomized,

placebo-controlled clinical trial, the efficacy and safety of radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in patients with CP.

2. Methods

2.1. Subjects

Fifteen patients participated in the study. We evaluated 12 men and 3 women, aged between 10–46 years (mean age 31). Patients were recruited in ASPACE Barcelona, using the following inclusion criteria: Patients with spastic CP. Time gap of at least 9 months since the last botulinum toxin injection. Ability of subject or legal respondent to give written informed consent after being told of the potential benefits and risks of participating in the study. The 15 patients presented 40 spastic muscles. Distribution: 6 biceps brachii, 6 wrist flexors, 5 hip adductors, 10 gastrocnemius, 10 soleus and 3 hamstrings. This clinical trial has been approved by the ethics committee of the Ramon Llull University. All patients provided informed written consent.

2.2. Evaluation protocol

At each clinical visit, range of motion and Ashworth Scale were performed.

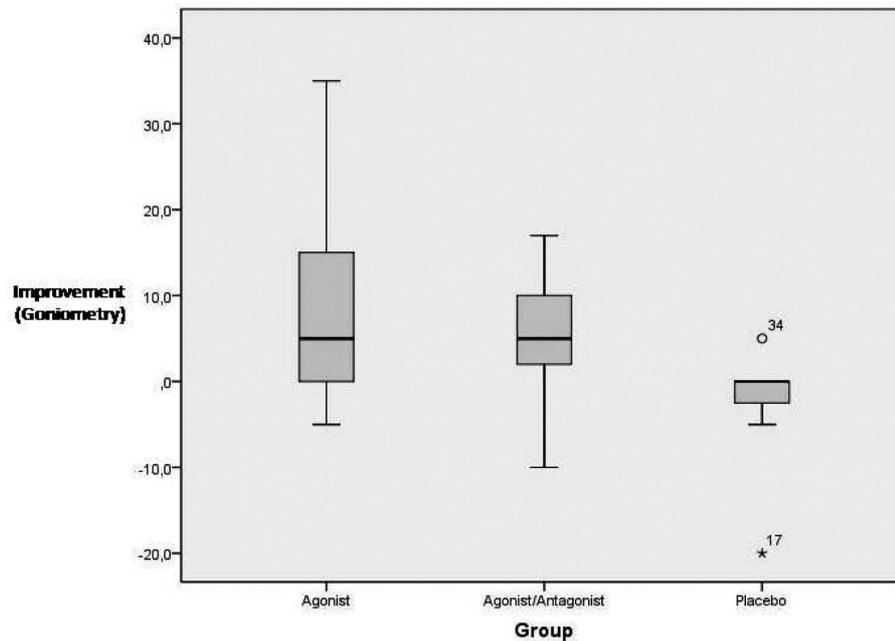


Fig. 2. Lower limb muscles. Median improvement 2 months after receiving treatment. There are significant differences between group agonist and group placebo.

2.3. Clinical examination

Spasticity was evaluated in the lower limbs by passive range of motion with a goniometer, and in the upper limbs with Ashworth scale (0: no spasticity to 4: severe spasticity). Patients were examined by the same physiotherapist, who was blindfolded. One visit was performed on each occasion, by the same physiotherapist. The examination was performed with the patient lying on the stretcher.

2.4. Study procedure

This study is a randomized, placebo-controlled clinical trial. In each subject, the evaluation was performed immediately before application and after one, two and three months of treatment. The non-parametric Mann-Whitney U test for independent samples was used for statistical analyses. 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 (see Figs 1 and 2).

2.5. Shock wave instrumentation and treatment

Swiss Dolor Clast (EMS-Switzerland). The patients were treated in 3 sessions at intervals of one week. Number of impulses: 2000 in each spastic muscle in group I and 4000 in group II (2000 in spastic muscle and 2000 in antagonist muscle). Energy flux density: 0.10 mJ/mm². (2 bar). Frequency: 8 Hz.

3. Results

There are not significant differences between group I (rESWT in spastic muscle) and group II (rESWT in spastic muscle + rESWT in antagonist muscle). On the spastic muscles from upper limbs there are significant differences ($p = 0.05$) between group I (rESWT in spastic muscle) and group III (placebo), (Fig. 3). On the spastic muscles of lower limbs there are significant differences ($p = 0.044$) between group I (rESWT) and group III (placebo), (Fig. 4). On the spastic muscles of lower limbs there are significant differences ($p = 0.043$) between group II (rESWT in spastic muscle + rESWT in antagonist muscle) and group III (placebo). A significant decrease in the Ashworth Scale, an increase in the range of motion, were observed in all patients that were treated with rESWT. Observed side

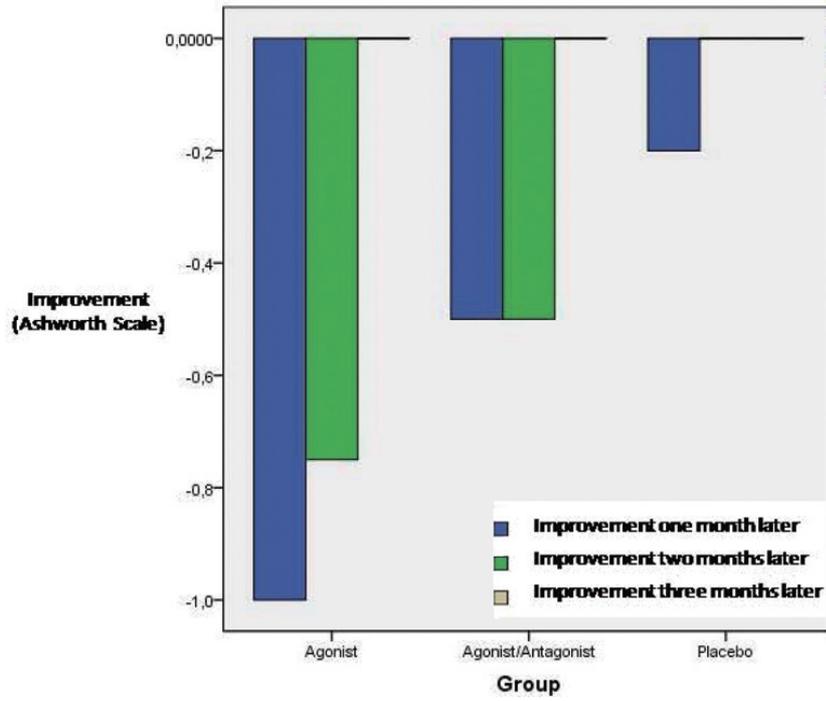


Fig. 3. Comparison of median improvement between the first and third month after treatment in upper limb muscles.

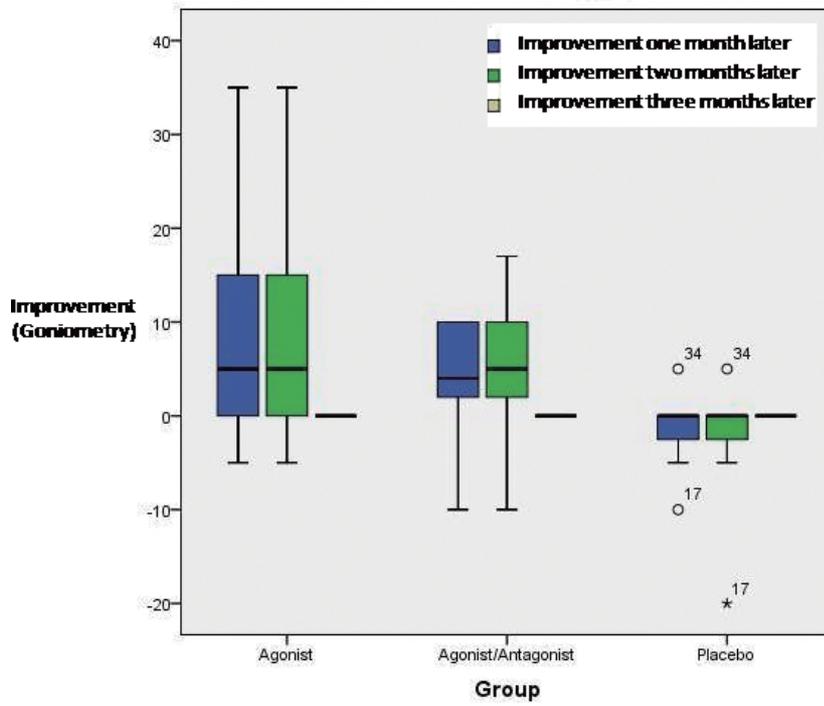


Fig. 4. Comparison of median improvement between the first and third month after treatment in lower limb muscles.



Fig. 5. rESWT application in gastrocnemius.



Fig. 6. rESWT application in wrist flexors.

effects were 3 small superficial hematomas, petechiae, and light pain during the therapy expressed by 3 patients. All side effects were tolerated by all the patients and disappeared after 1–7 days.

4. Discussion

This study presents interesting ideas about the usefulness of rESWT in the treatment of spasticity in cerebral palsy patients, as a noninvasive technique, usually painless and without important side effects. Obtained clinical results were interesting, thus in the active stim-

ulation group a significant reduction in muscle tone after treatment with rESWT was detected, however, in the placebo group no effect was observed. Positive results were maintained for at least 2 months after treatment and at three months the results were the same as those obtained just before treatment. All the patients finished the study. At the end of follow-up, they were asked about willingness repeat the experience and all of them answered affirmatively. The mechanism of shock wave therapy on spastic muscles is still unknown. Basic research and further large randomized controlled studies are necessary to support the results of this clinical trial.

5. Conclusion

This experimental study shows that the treatment with rESWT is more effective than placebo in decreasing spasticity of patients with CP, with an effect that is maintained up to two months later. At three months, it loses its effectiveness (Figs 5, 6); therefore, it would be interesting to do another rESWT application before three months.

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