Ultrasound in Med. & Biol., Vol. ■, No. ■, pp. 1–14, 2016

0301-5629/$ - see front matter

ELSEVIER

http://dx.doi.org/10.1016/j.ultrasmedbio.2016.03.006

● *Original Contribution*

THE EFFECT OF RADIAL EXTRACORPOREAL SHOCK WAVE STIMULATION ON UPPER LIMB SPASTICITY IN CHRONIC STROKE PATIENTS: A SINGLE–BLIND, RANDOMIZED, PLACEBO-CONTROLLED STUDY

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(*Received* 4 *September* 2015; *revised* 3 *March* 2016; *in final form* 11 *March* 2016)

Abstract—The main purpose of this study was to determine the clinical, electrophysiological and thermal effects of radial extracorporeal shock wave (rESW) stimulation on upper limb muscles affected by spasticity in patients with chronic stroke. Patients included in the study were randomly assigned into the following two groups: 30 patients stimulated with active rESW (A); and 30 patients stimulated with placebo rESW (B). All patients were analyzed using the Modified Ashworth Scale (MAS) to test the spasticity levels of the elbow (E), radio carpal (RC) and fingers (FF) joints; surface electromyography (sEMG) was performed for the resting bioelectrical activity registration of the flexor carpi radialis (FCR) and flexor carpi ulnaris (FCU) muscles; and infrared thermal imaging (IRT) was used to assess the temperature distributions of the carpal flexor muscles (CFM). All assessments were performed at baseline (t_0), immediately after rESW (t_1) as well as 1 and 24 h following its finalization (t_2 and t_3). Patients treated with active rESW showed a statistically significant reduction in the MAS score for the RC joint at t_1 and for the FF joints at t_1, t_2 and t_3 ($p < 0.05$). A significant decrease in sEMG activity was observed in the FCR and FCU muscles at t_1, t_2 and t_3 ($p < 0.05$); significant increases in the mean and maximum values of the IRT detection was observed using inter-group comparisons in t_2 and t_3 ($p < 0.05$). No significant alterations were observed in patients after placebo rESW stimulation ($p > 0.05$). Applications of rESW demonstrating positive effects at reducing the level of spastic hypertonia of the upper limb muscles in patients with chronic stroke. ESW treatments should be considered as a potential anti-spastic effect to regulate vasculature. (E-mail: r.dymarek@gmail.com)

Key Words: **Radial extracorporeal shock wave, Chronic stroke, Upper limb spasticity, Clinical assessment, Modified Ashworth Scale, Electrophysiological examination, Surface electromyography, Trophic conditions, Infrared thermography.**

INTRODUCTION

Spasticity is a form of muscle hypertonia as that results in the pyramidal tract when corticoreticulospinal fibers (extrapyramidal tract) are damaged, which gives an upper motor neuron (UMN) syndrome due to a lesion of the central nervous system (brain and/or spinal cord) (Thibaut et al. 2013). Spasticity is characterized by a velocity dependent increases in tonic stretch reflexes with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflexes. This spasticity is one of the clinical signs of the UMN syndrome (Lance 1980).

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Spasticity is one component of UMN syndrome; however, in addition to reflex hypertonia, patients with UMN syndrome also suffer from a non-reflex hypertonia due to connective tissue changes (Gracies 2005). The pathophysiology of spasticity is still poorly understood, but the accessory motor pathways clearly play an important role because an isolated, purely cortical lesion does not cause spasticity (Bähr and Frotscher 2012; Florman et al. 2013). Electromyography (EMG) studies have shown that the reflex-mediated increase in muscle tone reaches its maximum between one and three mo after stroke (Sommerfeld et al. 2004).

A loss of muscle strength and motor control results from a muscle weakness due to UMN syndrome; by contrast, contracture can result from joint, muscle or soft tissue limitations (Brainin 2013). The most common spasticity-related complications include sensory disturbances, chronic neuropathic pain, bone deformities with demineralization, severe muscle spasms, fibrosis of muscle fibers as well as muscle atrophy with their rheological changes (Carda et al. 2013; Hafer-Macko et al. 2008; Pang et al. 2010; Pang et al. 2013). Spasticity can be affected by a number of factors, such as structural changes in muscle and tendon fibers along with mechanical or morphologic changes of intra- and extracellular components (Dietz and Sinkjaer 2007).

An extracorporeal shock wave (ESW) is characterized by a sequence of single acoustic pulses that generate transient pressure disturbances with high peaks of pressure, fast pressure rises short time of durations and rapid propagations in 3-D space (Cleveland et al. 2007; Foldager et al. 2012; Speed 2014). In brief, there are the two different types of ESW stimuli based on their propagation pattern: focused extracorporeal shock wave (fESW) and unfocused extracorporeal shock wave, also called as radial extracorporeal shock wave (rESW). The fESW is well studied and has been successfully used since the late 1980s. On the other hand, rESW is a very new technology, first applied in 1999, and the biological mechanisms of its action are still poorly documented due to fewer available Level 1 and Level 2 studies (Foldager et al. 2012; Marinelli et al. 2015). This is the reason why we decided to choose the rESW device for the treatment of post-stroke spasticity in this study.

Recent studies have indicated that ESW has been successfully used to treat spastic hypertonia in patients with UMN lesions associated with brain injuries (Amelio and Manganotti 2010; El-Shamy et al. 2014; Gonkova et al. 2013; Moghtaderi et al. 2014). The list of clinical indications for ESW treatment and research areas of investigation are continuously evolving and adapting to a variety disorders including limb spasticity, especially in post-stroke survivors. To the best of our knowledge, there is a lack of studies assessing resting bioelectrical activity examination or surface temperature regulations of muscles affected by UMN lesions and treated with rESW stimulation.

Thus far, only one randomized clinical trial has examined the clinical effectiveness of an rESW pneumatic device in post-stroke upper limb spasticity conducted by Daliri et al. (2015). In addition, there is only one non-randomized prospective clinical trial by Kim et al. (2015) where the rESW was used in post-stroke lower limb spasticity. Moreover, neurophysiological or rheological mechanisms of ESW actions according to its anti-spastic features in patients affected by post-stroke muscle hypertonia are still under investigation. Our choice of the rESW pneumatic device in this study is strongly connected with the presence of its insufficient scientific evidence determining beneficial therapeutic effects in reduction of spasticity, especially after stroke.

The fESW is generated electromagnetically, electrohydraulically and piezoelectrically with rapidly increased pressure under 10 ns, reaching 100–1000 bars (10–100 MPa) with absorption to 12 cm (more invasive with the highest energy exposure in the focal area of deep zones). On the other hand, the rESW is pneumatically generated by ballistic devices located inside the generator that create linear pressures with low energy values. The energy is produced by the pressure wave while compressed air accelerates the cartridge strikes on the top of the applicator. The pressure of rESW slowly increases, up to 5 μs, reaches 1–10 bars (0.1–1 MPa) and is absorbed to a depth of 3 cm (less invasive and fixed in the region of interest at the surface) (Dymarek et al. 2014; Mittermayr et al. 2012).

After establishing the beneficial potential of ESW on various chronic tendinopathies, numerous researchers have investigated its usefulness in treating many musculoskeletal disorders including plantar fasciitis (Lee et al. 2013), Achilles tendinopathy (Rasmussen et al. 2008), patellar tendinopathy (van Leeuwen et al. 2009), pelvic pain syndrome (Zimmermann et al. 2009), cervical spondylosis (Lin et al, 2015), carpal tunnel syndrome (Romeo et al. 2011), lateral and medial epicondylitis (Dingemanse et al. 2014), calcifying shoulder tendinitis (Ioppolo et al. 2013), chronic proximal hamstring tendinopathy (Cacchio et al. 2011) and myofascial pain syndrome with trigger points (Moghtaderi et al. 2014).

The first purpose of the study was to assess the clinical effects of rESW on muscle spasticity levels in the Modified Ashworth Scale (MAS) assessment (primary outcome). The second purpose was to investigate the resting bioelectrical activity of treated muscles in the surface electromyography examination (sEMG), as well as to detect thermal conditions in the region of tested muscles in the infrared thermal imaging (IRT) (secondary outcome). It was assumed that a single session of rESW treatment would lead to reduction of spasticity levels in MAS, and would help to diminish the resting bioelectrical activity in sEMG and improve trophic conditions in the IRT.

METHODS

Ethical approval and design

This study is a prospective, single-blind, placebo-controlled, randomized clinical study to evaluate the effects of rESW on upper limb spasticity in chronic stroke patients. The research was conducted at the Department of Neurologic Rehabilitation of the Provincial Specialist Hospital in Wroclaw, Poland during the period from 2 October, 2012 to 28 June, 2015. The study was conducted