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● *Original Contribution*

THE EFFECTIVENESS OF RADIAL EXTRACORPOREAL SHOCK WAVES FOR TREATMENT OF CARPAL TUNNEL SYNDROME: A RANDOMIZED CLINICAL TRIAL

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Abstract—This study examined the effectiveness of radial extracorporeal shock wave therapy in the treatment of carpal tunnel syndrome (CTS). Forty patients with mild to moderate CTS were allocated to two groups: (i) shock wave + wrist splint and (ii) wrist splint. Patients used wrist splints followed by three sessions of low-energy shock wave therapy in the intervention group and wrist splints alone in the other group. The QuickDASH Questionnaire, visual analogue scale and nerve conduction studies were used to evaluate the patients before the study and at 3, 8 and 12 wk after the start of the treatment. At the end of the study, both groups saw the same clinical benefits. However, a significantly greater improvement in the median nerve distal sensory latency was noted in the shock wave group compared with the control group. We suggest that application of shock wave with alternative protocols may be effective in the treatment of CTS in future studies. (E-mail: tannaz.ahadi@yahoo.com) **© 2016 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Carpal tunnel syndrome, Splint, Median neuropathy.**

INTRODUCTION

Carpal tunnel syndrome (CTS), caused by compression of the median nerve in the carpal tunnel, is the most common peripheral entrapment neuropathy (Papanicolaou et al. 2001).

The classic symptoms of CTS include numbness, tingling and pain of the three radial digits, which can progress to permanent sensory and/or motor loss in the later stages (Walter et al. 2008). Although there are many conservative methods of management, such as a wrist splint, steroid injections and laser therapy, their effectiveness is minimal (O'Connor et al. 2003).

Wrist splints traditionally have been used as one of the most common treatments for CTS with a reported success rate of 31%–67%, if applied during early stages of the disorder (Premoselli et al. 2006).

A newly emerging, non-invasive therapeutic method in the treatment of CTS is extracorporeal shock wave (ESW) therapy. Over the last 10 y, ESW therapy has become a common and successful method in the treatment of various inflammatory musculoskeletal disorders, such as plantar fasciitis and lateral epicondylitis and so on (Romeo et al. 2014; Wang 2003; Wang and Chen 2002; Wang et al. 2002a, 2002b; Rompe et al. 2001).

The potential benefits of ESW therapy in the management of peripheral neuropathies have recently received greater attention. Shock waves promote axonal regeneration of peripheral nerves through several molecular reactions (Hausner and Nogradi 2013; Hausner et al. 2012; Lee and Cho 2013). Recently, radial shock waves demonstrated their effectiveness in neuropathic pain of rats with chronic constriction injuries (Fu et al. 2014).

Radial extracorporeal shock waves (RESWs) differ from focused extracorporeal shock waves (FESWs). Focused shock waves require accurate identification of the targeted area while the radial waves disperse eccentrically from the applicator tip without focusing at a targeted spot. The energy produced by RESWs is highest at the skin surface, diverging and weakening as it penetrates

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deeper (Romeo et al. 2014). A recent systematic review reported that some advantages of RESW therapy over traditional FESW therapy include a larger treatment area, no need for exact localizing the target area, no requirement for local anesthesia and low cost (Chang et al. 2012).

In recent years, few studies have reported the use of shock wave therapy as an alternative management for treating CTS (Notarnicola et al. 2015; Paoloni et al. 2015; Seok and Kim 2013).

Seok and Kim (2013) compared the efficacy of ESW therapy with local steroid injection in the treatment of CTS. According to the results of this study, shock waves may be as effective as local steroid injection in relieving the symptoms.

Paoloni et al. (2015) compared the short-term efficacy of ultrasound (US) therapy and ESW therapy on mild and moderate CTS and found the patients in the ESW group showed greater pain improvement at a 12-wk follow-up compared with both the US and cryo-US groups. Notarnicola et al. (2015) examined the efficiency of shock wave therapy versus dietary supplements in managing CTS and reported that both treatments are effective in controlling of the symptoms and improving the evolution of CTS. Another clinical trial evaluated the effect of ESW on CTS surgical complications (pillar syndrome), reporting pain regression and improvement of surgical scarring (Romeo et al. 2011).

However, the above studies used focused shock waves, and none has entirely proven the effects of ESW therapy on CTS. Recently, Wu et al. (2016) evaluated the effect of radial shock waves on CTS patients and demonstrated that RESW therapy is an effective method for relieving pain and disability in patients with CTS. ESW therapy is a potentially novel approach for treating CTS. While a few papers have reported the effects of ESW therapy on CTS, no treatment protocol for RESW therapy has been established. Several questions, including the most effective and safe intensity of ESW therapy, remain unanswered, and further studies need to be conducted to resolve these queries and to confirm the results of the previous studies. Because of the potential risk of nerve damage and intolerance of a high-energy protocol (used in the Wu et al. study) by our patients, we decided to try a low-dose, painless protocol.

We conducted a prospective randomized, controlled study to assess the effect of low-dose painless RESW therapy protocol for treating CTS.

MATERIALS AND METHODS

Participants

Forty patients aged between 18 to 70 y with mild and moderate CTS were recruited during a randomized, single blinded, controlled clinical trial method. Participants were visited in the physical medicine and rehabilitation clinic at Firoozgar Hospital. Inclusion criteria were typical signs and symptoms of CTS, including paresthesia, numbness or pain in the median nerve distribution for more than 1 mo, visual analogue scale (VAS) ≥4, positive Tinel's sign or Phalen's test in physical examination and confirmed diagnosis of mild to moderate CTS with electrophysiological study. A positive Tinel's sign is described as a tingling sensation in the nerve anatomic distribution, which occurs as a result of light percussion over a nerve. Phalen's test is described as positive when full flexion of the wrist for 60 s causes paresthesia in the territory of the median nerve (Urbano 2000).

Pregnant women and patients with severe CTS, previous carpal tunnel release surgery, corticosteroid injection in carpal tunnel within the last 3 mo and a history of wrist fractures were excluded. In addition, people with abnormal electrophysiological findings other than CTS, such as cervical radiculopathy or peripheral neuropathy, were also excluded.

Ethical consideration

All participants enrolled in this study were well informed regarding the methods, aims and possible side effects of treatments. This study was approved by the Ethics Committee and was registered at the Registry of Clinical Trials (IRCT2014083118991 N1). After written informed consent was obtained, patients were randomized into two groups: (i) RESW therapy + wrist splint and (ii) wrist splint. We used a block randomization method with a 1:1 ratio according to severity of disease (mild or moderate CTS).

Procedures

After pre-treatment evaluations and to provide fundamental treatment for CTS, a night wrist splint was prescribed for each patient in both groups. A Neoprene wrist splint with metal bar support was firmly fixed on the wrist in 0–5° extension. Patients were advised to avoid repetitive flexion and extension of the wrist. In cases of bilateral CTS to comply with ethical codes, the wrist splint was prescribed for both hands. However, only the hand with more severe symptoms was evaluated.

In the intervention group, participants underwent three RESW therapy sessions once per wk for 3 consecutive wk. The shock wave probe was placed perpendicularly on the patient's palm over the median nerve on the carpal tunnel after application of the coupling gel. The median nerve was localized by anatomic landmarks on the wrist (between the flexor carpi radialis and palmaris longus tendons). Due to pain and intolerance of a high-energy protocol by our patients, we used a painless, low-dose protocol as a pilot in a few patients. This