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ORIGINAL RESEARCH ARTICLE

The Effectiveness of Extracorporeal Shock Wave Therapy *vs.* Local Steroid Injection for Management of Carpal Tunnel Syndrome

A Randomized Controlled Trial

ABSTRACT

Seok H, Kim SH: The effectiveness of extracorporeal shock wave therapy *vs.* local steroid injection for management of carpal tunnel syndrome: A randomized controlled trial. Am J Phys Med Rehabil 2013;92:327–334.

Objective: Local corticosteroid (CS) injection has been widely used to treat carpal tunnel syndrome, but its invasiveness can cause several complications. In this study, the authors tested the efficacy of a new treatment method, extracorporeal shock wave therapy (ESWT), compared with CS injection.

Design: The authors carried out a randomized controlled trial comparing one session of ESWT (1000 shots at the maximal tolerable intensity) with one session of CS injection in 36 patients with carpal tunnel syndrome. Outcome measures including nerve conduction studies, a visual analog scale, and the Levine Self-assessment Questionnaire were performed at baseline and at 1 and 3 mos after treatment.

Results: At baseline, there were no significant differences between the groups with respect to the outcome parameters. Both groups showed a significant reduction in the visual analog scale at 1 and 3 mos after treatment compared with baseline. For the symptom severity score on the Levine Self-assessment Questionnaire, the ESWT group showed a significant reduction at 1 and 3 mos after treatment, whereas the CS injection group showed a significant reduction at 3 mos after treatment. For the nerve conduction parameters, there were mild but no significant improvements in the ESWT group, whereas the sensory nerve conduction velocity, the sensory nerve action potential amplitude, and the distal sensory and motor latencies of the median nerve were significantly improved in the CS injection group.

Conclusions: ESWT can be as useful as CS injection for relieving symptoms of carpal tunnel syndrome. Furthermore, in contrast to CS injection, it has the merit of being noninvasive.

Key Words: High Energy Shock Waves, Carpal Tunnel Syndrome, Nerve Conduction, Nitric Oxide

Carpal tunnel syndrome (CTS) is a clinical disorder caused by compression of the median nerve in the wrist. The syndrome is common, and it can be associated with substantial disability. In cases of mild to moderately severe CTS, corticosteroid (CS) injections beneath the transverse carpal ligament are the preferred treatment option. CS injections are administered to reduce the inflammation and swelling of the soft tissue around the median nerve (e.g., the flexor tenosynovium) and thereby reduce the pressure on the median nerve.[1] However, the invasiveness of CS injections can lead to several complications, including infection, tendon injury, and needle injury to the median nerve, which manifest as severe pain with lasting or permanent sensory loss.[2,3]

Steroids also limit tenocyte function by reducing collagen and proteoglycan synthesis, which reduces the mechanical strength of the tendon, leading to degeneration.[4] On this account, several noninvasive modalities have been suggested, including nonsteroidal anti-inflammatory drugs and bracing the wrist to prevent extremes of flexion and extension. However, the efficacy of these interventions is not significant or only continues for a short time.[5]

Shock waves are defined as a sequence of single sonic pulses characterized by a high peak pressure (100 MPa), fast pressure rise (<10 nsecs), and short duration (10 μsecs). Extracorporeal shock wave therapy (ESWT) is a noninvasive procedure that uses single-pulse acoustic waves, which are generated outside the body and focused on a specific site within the body.

Several studies have demonstrated that ESWT is an efficient and long-lasting pain-reducing method in soft tissue diseases such as plantar fasciitis and Achilles tendinopathy.[6,7] Although the antinociceptive mechanisms of ESWT have yet to be elucidated, ESWT may induce analgesia in the nerve fiber itself through biochemical changes and may decrease inflammation of the soft tissues.[8–10] The authors assumed that these effects of ESWT may reduce the CTS manifestations.

To the best of the authors' knowledge, no reported studies have investigated the effectiveness of ESWT for the treatment of entrapment neuropathies, including CTS. Thus, the authors investigated the efficacy of ESWT for the treatment of CTS and compared the efficacy of ESWT with that of local CS injection, with a follow-up of 3 mos.

METHODS

All participants were informed of the procedure and the objectives of this study as well as possible complications. Only patients who gave informed consent were selected. Ethical approval was obtained from the institutional Human Research Ethics Committee.

Participants

Patients at the university medical center electromyography clinic were enrolled between August 2010 and July 2011. All participants were at least 19 yrs of age, had a positive Tinel sign or Phalen test, and had numbness and tingling in at least two of the first, second, and third digits. The inclusion criterion was the presence of mild to moderately severe CTS, confirmed by electrophysiologic studies.[11]

Patients with abnormal median sensory nerve conduction velocity across the carpal tunnel but with normal median motor distal latency were classified as having mild CTS. If the conduction speed of the median sensory and motor nerve fibers across the carpal tunnel was abnormal but the sensory nerve action potentials were still present, the subjects were categorized as having moderately severe CTS. The exclusion criteria were the presence of thenar atrophy, pregnancy, previous carpal tunnel decompression surgery, previous CS injection to the carpal tunnel, or a history of trauma to the wrist or arm.

Each participant was randomly assigned to the ESWT or the local CS injection group using the random number generation function in a commercially available software program (Excel; Microsoft, Redmond, WA). If the participants showed bilateral CTS, only the hand with the more severe CTS was selected for treatment. The Participants were instructed to refrain from using any other conservative treatment, including wrist splinting and anti-inflammatory medications, during their participation in this study.

Interventions

ESWT Group

The patient's forearm was placed on a table with the palm facing up, and the forearm, hand, and fingers were restrained by a strap using a thermoplastic splint.

The point of the ESWT site was located by ultrasonography (ACCUVIX V10 system; Medison, Seoul, Korea) interfaced with a 5-12 MHz linear array transducer, and the median nerve was visualized at the line of the proximal carpal tunnel (scaphoid-pisiform level).

Each patient received one session of ESWT that comprised 1000 shocks at a frequency of 360 shocks

per minute (PiezoWave; Richard Wolf GmbH, Knittlingen, Germany; Fig. 1). The probe was oriented perpendicular to the patient's palm, and ultrasound gel was used as a coupling agent. The energy level was set at the maximum level tolerated by the patient (0.09 ~ 0.29 mJ/mm^2).

Local CS Injection Group

The affected wrists were first cleaned with isopropyl alcohol and anesthetized locally using 1 ml of lidocaine by injection. Under ultrasonographic guidance, a 23-gauge needle was inserted at the proximal wrist crease, just ulnar to the palmaris longus tendon, at a 30-degree angle to the skin and aiming toward the index finger. One milliliter of triamcinolone acetonide (40 mg) was injected into the area surrounding the median nerve by experienced staff. Each patient was injected only once.

Evaluations

The investigators who evaluated the electrodiagnostic and clinical measurements were blinded to the allocated treatments and to each other. All evaluations were repeated at baseline and at 1 and 3 mos after treatment by the same investigator.

Nerve Conduction Studies

All nerve conduction studies (NCSs) were performed in a room with the temperature kept at 25°C. The recorded parameters included the sensory nerve action potential amplitude, the compound muscle action potential amplitude, the median sensory distal latency, the median motor distal latency, and the median sensory nerve conduction velocity.

The motor NCS of the median nerve was performed by stimulating the median nerve in the wrist and recording over the thenar eminence muscles using disposable silver/silver chloride surface strip electrodes. The maximum normal limit of the median motor distal latency was 4.2 msecs.[12] The sensory NCS was performed by stimulating the median nerve at the palm and proximal to the wrist while recording the response over the third digit. The minimum normal limit of the median sensory nerve conduction velocity was 50 m/sec.

During the initial evaluation, all participants underwent electromyography of the paracervical muscles and the median nerve–distributed muscles to rule out cervical radiculopathy or other median nerve entrapment neuropathies. The ulnar nerve and superficial radial nerve were also evaluated through electrophysiologic studies to rule out other peripheral neuropathies that could cause similar hand symptoms. The participants who showed abnormal electrodiagnostic findings other than CTS were removed from the study.

Symptoms and Sensory Measures

The symptom assessment parameters were a 10-cm visual analog scale (VAS) and the Levine Self-assessment Questionnaire (LSQ). The LSQ, which is the most commonly used outcome measure in the assessment of patients with CTS, provides a symptom severity score, based on 11 questions covering the symptoms of CTS, and a functional status score, with 8 questions based on the level of difficulty in performing activities of daily living. The scores are based on a scale of 1 to 5, with 5 being the most difficult.[13]

The Semmes-Weinstein testing was performed on the middle finger of all patients using a Semmes-Weinstein monofilament kit containing five filaments (WEST-HAND, Riverdale, NY). The subjects were asked to stabilize their hands over a table and to keep their eyes closed for the duration of the test. Each filament, starting with the smallest caliber, was tested over the pulp of the digits. The filament was applied perpendicularly for 1 sec in three trials. The subjects were asked to indicate the area where the filament was felt. A positive response in at least two of the three trials marked the sensory threshold. The sensory threshold of all fingers was examined in random order so that it was unpredictable to the subjects. The authors used the test results for the third digit, where the sensory NCS was also performed for data analysis, with the following range of results used for scoring: normal (2.83 filament), corresponding to a score of 1; diminished light touch (3.61 filament), corresponding to a score of 2; diminished protective sensation (4.31 filament),

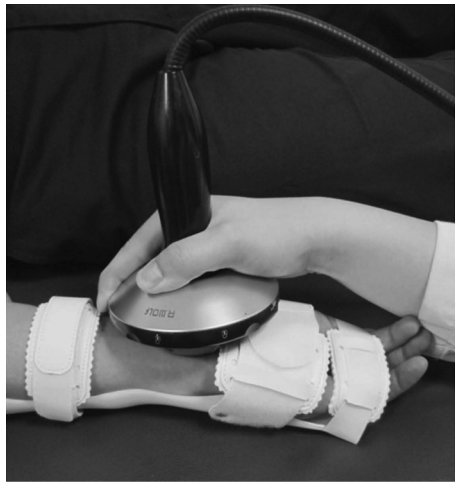

FIGURE 1 *Application of extracorporeal shock wave therapy (ESWT) to a patient's wrist, which was restrained in a thermoplastic splint.*

TABLE 1 Patient characteristics

	ESWT Group (n = 15)	Injection Group (n = 16)
Age, mean ± SD, yrs	54.03 ± 19.47	49.67 ± 18.83
Sex, male/female	3/12	2/14
Dominant hand lesion, %	75	72.7
Duration of symptoms, mean ± SD, wks	9.76 ± 3.57	10.15 ± 2.30

ESWT indicates extracorporeal shock wave therapy.

corresponding to a score of 3; loss of protective sensation (6.45 filament), corresponding to a score of 4; deep pressure sensation (6.65 filament), corresponding to a score of 5; and tested with no response, corresponding to a score of 6.

Statistical Analysis

All data were analyzed using SPSS for Windows version 15. Demographic data were analyzed by the Mann-Whitney U test for continuous data and by the χ^2 test for categorical data. The Wilcoxon's signed-rank test was used to compare the outcome measures within each group of subjects. The outcomes at each follow-up session were compared with the baseline values. Differences between the groups were investigated using the Mann-Whitney U test. Statistical significance was accepted at $P < 0.05$.

RESULTS

Patients

A total of 36 eligible participants, 25 women and 11 men, were enrolled. There were four patients with bilateral CTS in the ESWT group and two patients with bilateral CTS in the CS injection group. Three patients in the ESWT group and two patients in the CS injection group dropped out during follow-up.

Consequently, the results pertain to the 31 patients who completed the study (Table 1). The groups were similar in age, sex, proportion of dominant hand lesion, and duration of symptoms ($P > 0.05$).

Symptom Score

In this study, the VAS score was a mean (SD) of 7.06 (1.89) in the ESWT group and 6.87 (1.26) in the CS injection group. In the ESWT group, the VAS score showed a significant improvement at 1 mo (mean [SD], 4.56 [0.81]) and at 3 mos (4.18 [1.05]) of treatment. The CS injection group also showed a significant improvement at 1 mo (mean [SD], 4.13 [1.50]) and at 3 mos (3.31 [1.82]) of treatment (Fig. 2).

The mean (SD) symptom severity score as judged by the LSQ before treatment was 31.27 (11.41) in the ESWT group and 28.50 (10.01) in the CS injection group. In the ESWT group, the symptom severity score showed a significant improvement at 1 mo of treatment (mean [SD], 20.13 [6.24]; $P < 0.05$) and decreased to a mean (SD) of

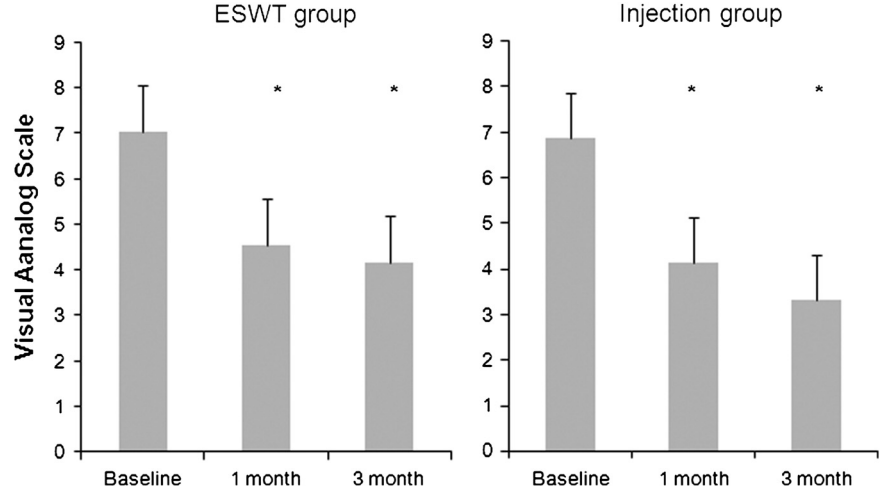

FIGURE 2 *Results of the visual analog scale. Box plots represent mean (upper margin of the box plots) and standard deviation (upper whisker). The significance was P < 0.05 compared with baseline. ESWT indicates extracorporeal shock wave therapy.*

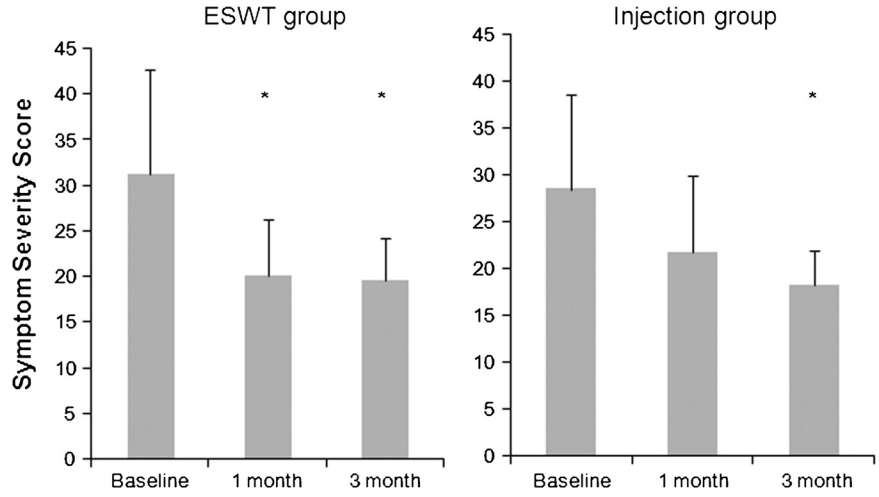

FIGURE 3 *Results of the LSQ symptom severity score. Box plots represent mean (upper margin of the box plots) and standard deviation (upper whisker). The significance was $P < 0.05$ compared with baseline. LSQ indicates Levine Self-assessment Questionnaire; ESWT, extracorporeal shock wave therapy.*

19.73 (4.48) by 3 mos after treatment ($P < 0.05$). In the CS injection group, there was a significant reduction in the symptom severity score at 3 mos, with a mean (SD) score of 18.25 (3.71; $P < 0.05$; Fig. 3). There was no significant difference between the two groups in either the VAS score or the LSQ symptom severity score initially and during follow-up. There was no significant difference in the LSQ functional status score within each group or between the two groups (Fig. 4).

Nerve Conduction Studies

In the NCSs, significant improvements were found only in the CS injection group (Table 2). The CS injection group showed improvements in the median sensory nerve conduction velocity, the sensory nerve action potential amplitude, the median sensory distal latency, and the median motor distal latency. However, a significant difference between the ESWT and CS groups was found only in the median sensory distal latency at 1 mo after treatment.

Sensory Thresholds

The sensory threshold checked by the Semmes-Weinstein monofilament at baseline was normal except for one person in the ESWT group who showed a score of 2 (diminished protective sensation). The sensory threshold did not change significantly after treatment in both groups. The only side effect

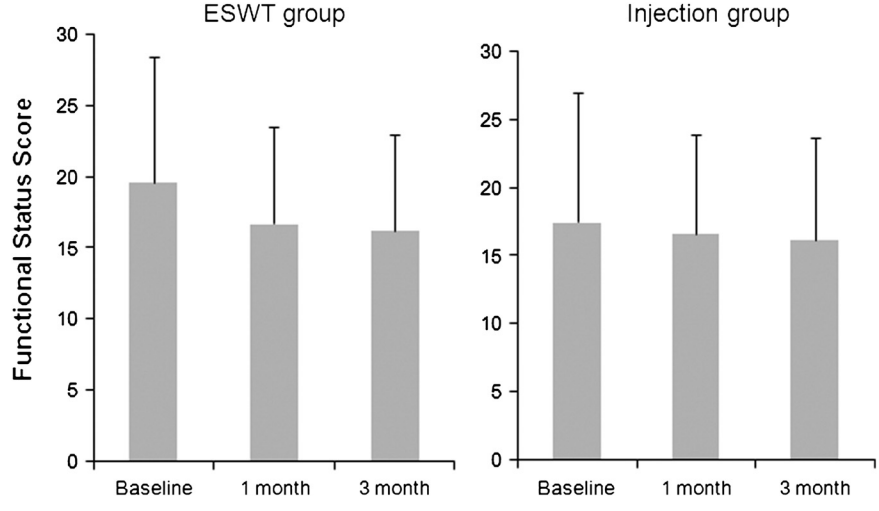

FIGURE 4 *Results of the LSQ functional status score. Box plots represent mean (upper margin of the box plots) and standard deviation (upper whisker). LSQ indicates Levine Self-assessment Questionnaire; ESWT, extracorporeal shock wave therapy.*

TABLE 2 Comparison of nerve conduction studies recorded at baseline and at 1 and 3 mos after treatment

	ESWT Group	Injection Group
NCV of median sensory nerve, m/sec		
Baseline	32.37 ± 8.85	34.35 ± 9.89
1 mo	32.18 ± 9.68	39.33 ± 8.69[a]
3 mos	35.78 ± 9.18	40.06 ± 9.38[a]
SNAP amplitude of median nerve, μV		
Baseline	18.73 ± 14.87	19.40 ± 13.43
1 mo	20.33 ± 15.38	25.75 ± 12.89[a]
3 mos	20.57 ± 12.01	24.79 ± 15.74
CMAP amplitude of median nerve, mV		
Baseline	8.11 ± 3.56	8.39 ± 3.29
1 mo	8.41 ± 2.81	8.59 ± 2.84
3 mos	8.50 ± 3.05	8.69 ± 3.04
DL of median sensory nerve, msec		
Baseline	4.03 ± 0.78	3.93 ± 1.35
1 mo[b]	4.01 ± 0.82	3.18 ± 0.91[a]
3 mos	3.88 ± 0.64	3.28 ± 0.90[a]
DL of median motor nerve, msec		
Baseline	4.94 ± 1.46	4.87 ± 1.33
1 mo	4.83 ± 1.30	4.26 ± 1.44[a]
3 mos	4.78 ± 1.35	4.37 ± 1.24

Values are presented as mean ± standard deviation.

[a] $P < 0.05$, compared with baseline.

[b] Significant difference between the ESWT group and the injection group, $P < 0.05$.

ESWT indicates extracorporeal shock wave therapy; NCV, nerve conduction velocity; SNAP, sensory nerve action potential; CMAP, compound muscle action potentials; DL, distal latency.

noted by the participants in either group was pain during the procedure, but it disappeared spontaneously within a few minutes.

DISCUSSION

Remarkable improvement in the VAS score and the symptom severity score in both the ESWT and CS injection groups was observed. The effects lasted for 3 mos, and no adverse effect was observed. In addition, there was significant improvement in the NCS parameters in the CS injection group.

CS injection is known to relieve local inflammation of the soft tissues around the median nerve in the carpal tunnel. This results in the release of pressure on the median nerve, leading to a reduction in pain and recovery of the NCS parameters.[14]

By comparison, there was only mild but not significant improvement in the NCS parameters in the ESWT group despite significant pain reduction. These findings suggest that the analgesic mechanism of the ESWT may be different from that of the CS injection in treating CTS.

Several recent studies have suggested that nitric oxide (NO) production induced by ESWT plays a critical role in suppressing the inflammatory process.[8,9,15] The sheer stress generated by ESWT stimulates constitutive NO synthase expression in soft tissues, leading to the production of physiologic levels of NO (<50 nM), which is a powerful suppressor of the inflammatory process.

Marriotto et al.[15] reported that in human umbilical vein endothelial cells treated with lipopolysaccharides/cytokines, mimicking inflammatory conditions, there was a rapid drop in both constitutive NO synthase activity and the level of NO. They reported that ESWT could stimulate constitutive NO synthase activity in these cell lines, resulting in the recovery of the physiologic level of NO, which suppressed ongoing inflammation.

In this study, ESWT may have been effective because it stimulated the suppressed constitutive NO synthase activity in the soft tissues around the median nerve, resulting in improvement of the local inflammation and release of the pressure on the median nerve. However, this effect may be less than that of the CS injection because the improvement in the NCS parameters, reflecting the release of pressure on the median nerve, was small in the ESWT group.

Another possible hypothesis is that pain reduction by ESWT occurs via the opioid/NO pathway. The mechanism of pain reduction by opioids is well known; it decreases nerve excitability and slows pain transmission, which is mediated by NO. Specifically, when an opioid peptide binds with a neuronal

receptor, it stimulates neuronal NO synthase, which produces NO. NO then acts on the nerve cell membrane to open potassium channels and reduce calcium influx; thus, it hyperpolarizes the membrane and stops pain transmission.[10,16]

Several recent studies have shown that ESWT can activate the neuronal NO synthase.[8,9] During ESWT, the NO produced by neuronal NO synthase may act as an opioid surrogate, thereby bypassing the need for opioid-receptor binding to achieve pain reduction. In this situation, the hyperpolarized nerve might show decreased excitability,[17] resulting in less improvement in the NCS parameters, despite the reduction in pain.

However, this study is the first that has attempted to evaluate ESWT for a peripheral entrapment neuropathy; the authors only evaluated the basal symptoms, signs, and routine NCS parameters. To support the hypothesis of this study, further study will be required to establish the exact mechanism of ESWT, including the change in the soft tissues around the median nerve (e.g., flexor tenosynovitis) after ESWT as evaluated by ultrasonography and the activity of NO synthase and the level of NO in the median nerve in CTS after ESWT.

Furthermore, several studies have indicated that the findings of the NCSs do not match the reduction in the symptoms in CTS patients. Chan et al.[18] reported that there were no statistically significant relationships between the electrodiagnostic findings and the patients' LSQ symptom severity scores. Longstaff et al.[19] also reported that no relationship existed between the symptoms and severity of electrophysiologic impairment. These discrepancies might have occurred because the NCS findings reflect significant demyelination or axonal loss in large-diameter nerve fibers, whereas the symptoms of CTS might be more closely related to the function of small-diameter nerve fibers, which were not assessed during the routine NCSs.

There was no significant change in functional status score in the ESWT and CS injection groups. This might have been because the functional status score reflects functional changes, which may have occurred more slowly and changed little, whereas the symptom severity score reflects paresthesia, pain, or both, which may have been rapidly alleviated by ESWT or CS injection.[20,21] In addition, the patients of this study had mild to moderately severe disease; thus, they may have initially had less restricted hand function.

Nearly all patients showed a normal sensory threshold level by the Semmes-Weinstein monofilament test; hence, there were no significant changes in this test. This was because the patients assessed in this study had only mild to moderately severe CTS. Furthermore, this study used a 5- instead of a 20-filament set, which might have decreased the authors' ability to detect tiny sensory changes.

The present study is believed to be the first ESWT trial in CTS patients. As a result, several limitations must be acknowledged, including the small sample size and lack of long-term follow-up. Alternative methods of applying ESWT (e.g., more than one session) and the evaluation of several parameters revealing possible mechanisms of action of ESWT will be important in future trials.

In conclusion, compared with CS injection, which was effective but invasive, ESWT also produced significant pain reduction in patients with CTS. ESWT is a potentially safe and noninvasive therapeutic interventional option for decreasing pain in patients with mild to moderately severe CTS. Future studies should examine the effects of ESWT in a larger group and with a longer follow-up period to confirm the initial findings of this study.

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