Original Article

Efficacy of Single-Session Focused Extracorporeal Shockwave Therapy in Patients with Moderate-Degree Carpal Tunnel Syndrome Versus Steroid Injection Therapy: A Single-Blind Randomized Controlled Trial

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ABSTRACT

Objectives: To compare the efficacy of single-session focused extracorporeal shockwave therapy (fESWT) and steroid injection in moderate-degree carpal tunnel syndrome

Study design: A single-blind, randomized controlled trial

Setting: Her Royal Highness Princess Maha Chakri Sirindhorn Medical Center, Nakhon Nayok, Thailand

Subjects: Patients with electrophysiological evidence of moderate-degree carpal tunnel syndrome.

Methods: Thirty-three patients with a combined total of 36 affected hands were enrolled. The mean age was 56.9 (10.68) years. Among the affected hands, 25 were right hands and 11 were left hands. Equal numbers of the thirty-six affected hands were randomly assigned to the experimental group, which received single-session fESWT with energy flux density ranging from 0.03 to 0.10 mJ/mm², 2,000 shocks per session at a frequency 6-8 Hz and the comparative group which received an injection of 10 milligrams of triamcinolone acetonide in 1 milliliter of solution. Outcomes were assessed using the following questionnaires: 1. Visual Analog Scale (VAS) for pain, 2. VAS for paresthesia, 3. Quick Disabilities of the Arm, Shoulder, and Hand (Quick DASH) scores, and 4. Total Boston Carpal Tunnel Questionnaire (BCTQ). Scores were recorded both before the interventions and at follow-up weeks 4, 8, and 12.

Results: There were no significant differences in demographic characteristics between the groups. After treatment, both groups showed reductions in VAS for pain, VAS for paresthesia, QDASH scores, and total BCTQ scores between baseline and weeks 4 and 12 follow-ups, with no statistically significant differences between the groups.

Conclusions: There was no evidence indicating a difference in clinical efficacy between single-session fESWT and steroid injection therapy in patients with moderate-degree carpal tunnel syndrome over a 12-week period. Therefore, noninvasive fESWT could be considered an option to which can avoid possible side effects of steroid injection.

Keywords: carpal tunnel syndrome, focused extracorporeal shockwave therapy, steroid injection

ASEAN J Rehabil Med. 2025; 35(1): 2-7.

Introduction

Carpal tunnel syndrome (CTS) is the most common peripheral nerve entrapment neuropathy in the upper extremity. It results from compression of the median nerve as it passes through the flexor retinaculum at the wrist. Common symptoms often include numbness or tingling in the palm areas supplied by the median nerve, specifically the tips of the thumb, index finger, and middle finger, and weakness during movement or while gripping objects.[1,2] This condition is found in approximately 2.7% to 5.8% of the general population, with a reported incidence of 276:100,000 annually.[1] The pathophysiology of CTS involves a combination of mechanical trauma, increased pressure, and ischemic damage to the median nerve within the carpal tunnel.[3]

The treatment options were categorized into non-surgical and surgical treatments, with the choice of modality based on the condition's severity. Non-surgical treatment was particularly effective for cases with mild symptoms, a duration of less than one year, and no muscle atrophy. Non-surgical treatments are well-supported by credible evidence for their efficacy including splinting and steroid injections. Both of these options are recommended as first-line treatments.[4,5] The exact mechanism of symptom relief is unknown, but the effects are believed to relate to the anti-inflammatory effects of steroids and to slightly decrease the risk of surgery during the first year; however, they might not continue to decrease the rate of surgery when follow-up continues for years.[6] Complications after administering steroid injections can include pain during injection, skin discoloration, muscle atrophy, infection or inflammation, finger ischemia, torn or damaged

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Received: June 15, 2024 Revised: August 8, 2024 Accepted: September 15, 2024

tendons, and median nerve injury. These complications can be temporary or permanent.[7,8]

Focused extracorporeal shockwave therapy (fESWT) is a relatively new method that has been used to treat a variety of musculoskeletal diseases.[9] fESWT is a noninvasive treatment that applies shockwaves to injured tissue to reduce pain and promote the healing process in tendinopathies and in bone and skin pathologies. Studies have confirmed its success in treating chronic plantar fasciitis, epicondylitis, and rotator cuff tendinitis. The working principle of fESWT involves repairing and stimulating the healing of tissues, nerves, and muscles at the molecular level. It triggers the release of local analgesia, which helps reduce pain symptoms.[10,11] Prior studies of ESWT have been conducted in CTS patients. For example, a study by Paoloni M. et al. comparing treatments for CTS between ultrasound therapy administered five times a week for three weeks and extracorporeal shockwave therapy administered once a week for three weeks found the group treated with shockwave therapy showed more significant improvement. In that study, outcomes were assessed using the Visual Analog Scale (VAS) score for numbness symptoms and found that the benefits of the shockwave therapy lasted up to three months.[12] A study by Seok et al. using one session of ESWT for CTS demonstrated improvements in pain scores and functional status comparable to local steroid injections. Additionally, in contrast to steroid injection, ESWT has the added benefit of being noninvasive.[13] Ke et al. suggested that ESWT is a valuable method for treating CTS and that results are more detectable in moderate degree than in mild degree CTS.[14] Currently, the treatment of CTS with ESWT does not yet have clearly defined standards, and studies in patients with moderate degree CTS are still limited. A previous study highlighted the potential benefits of fESWT over other treatments and showed that a single-dose radial ESWT was appropriate for treating mild to moderate CTS and that it provided longer-lasting benefits (24 months) in Thais.[15] If the results of the present study are confirmed by additional research, ESWT could be more widely applied to this group and could provide an alternative for those concerned about the side effects of steroid injections or who are apprehensive about injections, thus potentially improving their quality of life and expanding healthcare options.

Methods

Study design

This study was a single-blind, randomized controlled trial conducted at the Department of Rehabilitation Medicine, HRH Maha Chakri Sirindhorn Medical Center, Nakhon Nayok, Thailand. The Human Research Ethical Committee of Srinakharinwirot University approved it for human research (ethical approval number SWUEC/F-445/2020), and it was registered in the Thai Clinical Trials Registry on July 1, 2024 (Number TCTR20240704004).

Participants

Participants in this study were patients with clinical and electrodiagnostic evidence of a moderate-degree of carpal tunnel syndrome. Inclusion criteria were: 1) symptoms including numbness or pain in the palm, along with positive findings on the following tests: Phalen's test, Tinel's test, and the median compression test; 2) patients diagnosed with moderate carpal tunnel syndrome by electrodiagnosis who showed abnormal prolonged (relative or absolute) sensory or mixed-nerve action potential distal latency (orthodromic, antidromic, or palmar) Sensory nerve action potential (SNAP) amplitude below the lower limit of normal, and (relative or absolute) prolongation of median motor distal latency;[16] 3) age 18 years and over; 4) new patients who had not been treated with a steroid injection or other treatments, such as ultrasound, were excluded. Exclusion criteria included: 1) A history of physical therapy treatment in the previous six months, 2) Contraindications for fESWT, such as pacemaker implantation, and 3) Refusal to participate in the study. The number of participants included in this study was determined based on studies by Seok H. et al.[13] The sample size was calculated using Frison and Pocock's method and STATA version 14.0. The required sample size was determined to be 18 participants per group, a total of 36, which is sufficient to detect a clinically meaningful difference with 80% power at a 5% significance level and to account for a potential combined dropout rate of 20% due to loss to follow-up, non-compliance, and attrition. All participants provided written informed consent.

Randomization

Eligible patients who consented to participate in the research were randomly assigned to one of two groups using block randomization, which was generated in blocks of four using a random number generator from a free program at www.randomization.com

This study was a single-blind trial, with two research physicians involved in evaluating the treatment's effectiveness. The first research physician, who was not blinded, administered the treatment and assessed any treatment-related side effects. This physician provided treatment to both volunteer groups. The second research physician, who was blinded, was responsible for recording and documenting the assessment results of both groups.

Intervention

One group received treatment via an injection of 10 milli grams of triamcinolone acetonide (TA) in 1 milliliter of solution, administered at a 45-degree angle to the medial side of the flexor retinaculum using a 25-gauge needle. The other group received a single session focused on extracorporeal shockwave therapy using an electromagnetic cylindrical coil (Storz Medical AG, Tägerwilen, Switzerland). This device has an energy flux density ranging from 0.03 to 0.10 mJ/mm², a 6-8 Hz frequency, and delivers 2,000 pulses per session.

The shockwave probe was placed around the medial side of the flexor retinaculum area, and the energy intensity was adjusted to a level tolerable for the patient and was continued at that level until the treatment was completed. During the 12-week data collection period following this intervention, additional treatments such as CTS splints, physical therapy, or other medication were not allowed.

Outcome measurement

The primary outcome measures were the VAS for pain, the VAS for paresthesia, the Thai version of Quick DASH (QDASH) scores[17], and the Thai version of the Boston Carpal Tunnel Questionnaire (BCTQ) scores [18], along with the assessment of any adverse events at weeks 4, 8, and 12 after the treatment.

Statistical methods

This study analyzed the demographic characteristics of both groups using the mean (standard deviation). Demographic data were analyzed using Fisher's exact test for categorical variables, the Mann-Whitney U test for non-normally distributed continuous variables, and the independent t-test for normally distributed continuous variables. Generalized estimating equation (GEE) statistics was used to compare the primary outcome at baseline and at weeks 4, 8, and 12 after treatment of VAS score for pain including VAS score for paresthesia, QDASH scores, and total BCTQ scores reported with the mean difference and a 95% confidence interval. Statistical significance was set at $p < 0.05$. The characteristics of adverse events were recorded.

Results

Thirty-three patients, comprising 32 females and one male, with a total of 36 affected hands, participated in the study. Their ages ranged from 40 to 77 years, with a mean age of 56.94 (10.68). Three individuals had symptoms in both hands, while 30 had symptoms in only one hand. Symptoms were found in 25 right hands and 11 left hands. Of those, 25 hands were on the dominant side, and 11 were on the non-dominant side. There were no significant differences in demographic data between the groups ($p > 0.05$), as shown in Table 1.

The participants' data were compared at baseline and at weeks 4, 8, and 12 after treatment, as shown in Tables 2-5. It was found that there was a reduction in VAS for pain, VAS for paresthesia, QDASH scores, and total BCTQ scores at the week four follow-up in both groups. Nonetheless, no statistically significant differences were found between the groups ($p = 0.987, 0.254, 0.230, 0.194$). At the week eight follow-up, there was a decrease in VAS for paresthesia, QDASH scores, and total BCTQ scores compared to baseline, but there was an increase in those values compared to the week four follow-up in both groups. Only the VAS for pain in the fESWT group increased compared to baseline. Comparison between the two groups found no statistically significant differences ($p = 0.482, 0.261, 0.959, 0.390$, respectively). At the week twelve follow-up, it was found that there was a reduction in VAS for pain, VAS for paresthesia, QDASH scores, and total BCTQ scores in both groups. Nonetheless, when comparing the groups, the differences were found to be not statistically significant ($p = 0.300, 0.945, 0.645, 0.396$). Overall, there was a reduction in VAS for pain, VAS for paresthesia, QDASH, scores and total BCTQ scores in both groups. Comparison between the groups found no statistically significant differences ($p = 0.107, 0.073, 0.720$, and $p < 0.001$)

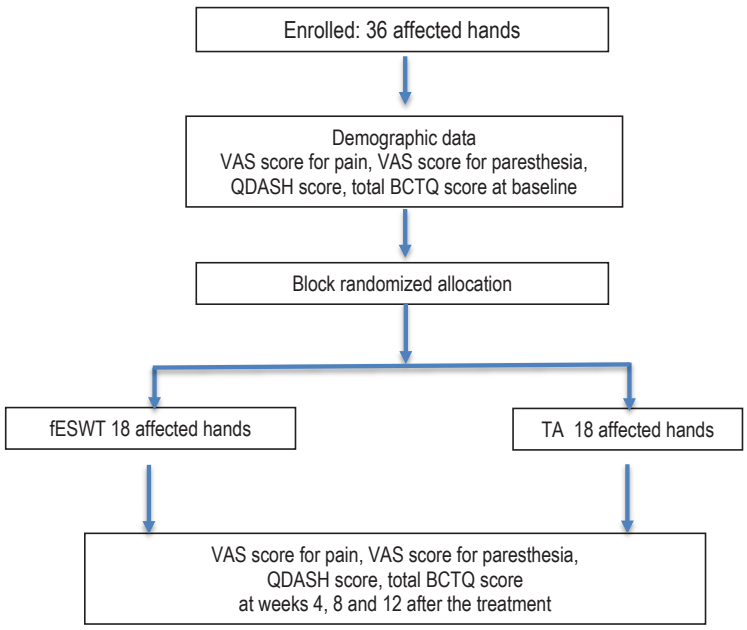

Figure 1. Flow diagram of the participants. fESWT, focused extracorporeal shockwave therapy; TA, triamcinolone acetonide

Table 1. A comparison of patient demographic data and baseline characteristics of the groups

Patient characteristic	fESWT group	TA group	*p-value
Gender (female/male)[1]	17/0	15/1	0.486
Age (year)[2]	55.67 (8.76)	58.22 (10.24)	0.426
Affected hand (left/right)[1]	5/13	6/12	1.000
Dominant hand (left/right)[1]	5/13	6/12	1.000
The nature of their occupation (light/heavy)[1]	12/6	6/12	0.094
Experienced nighttime symptoms (yes/no)[1]	5/13	9/9	0.305
Baseline time of CTS (month)[2]	9.83 (1.38)	9.11 (2.30)	0.350
Baseline VAS for pain[2]	2.57 (2.38)	2.55 (2.97)	0.977
Baseline VAS for paresthesia[2]	5.15 (1.79)	5.21 (2.60)	0.934
Baseline QDASH[2]	19.00 (12.06)	20.57 (15.68)	0.738
Baseline total BCTQ[2]	32.39 (8.21)	31.39 (8.82)	0.727

[1] Number, [2]Mean (SD), *$p < 0.05$ indicates statistical significance,
fESWT, focused extracorporeal shockwave therapy; TA, triamcinolone acetonide; CTS, Carpal tunnel syndrome; VAS, Visual analog scale; QDASH, quick disabilities of the arm, shoulder and hand; BCTQ, Boston Carpal Tunnel Questionnaire

Table 2. Comparison of visual analogue scale for pain at baseline and at weeks 4, 8, and 12 after treatment

Follow-up session	fESWT group Mean (SD)	TA group Mean (SD)	MD	(95% CI)	*p-value
Baseline	2.57 (2.38)	2.55 (2.97)	0.03	(-1.80-1.85)	0.977
Week 4	1.97 (2.39)	1.95 (2.42)	0.01	(-1.62-1.65)	0.987
Week 8	3.66 (6.95)	2.41 (2.73)	1.25	(-2.33-4.83)	0.482
Week 12	1.43 (1.93)	2.35 (3.15)	-0.92	(-2.69-0.85)	0.300
Overall	-	-	-0.06	(-1.4-0.01)	0.107

Generalized estimating equation (GEE) statistics, Mean (SD), *$p < 0.05$ indicates statistical significance
MD, mean difference; CI, confidence interval
fESWT, focused extracorporeal shockwave therapy; TA, triamcinolone acetonide

Table 3. Comparison of the visual analogue scale for paresthesia at baseline and at weeks 4, 8, and 12 after treatment

Follow-up session	fESWT group Mean (SD)	TA group Mean (SD)	MD	(95% CI)	*p-value
Baseline	5.15 (1.79)	5.21 (2.60)	- 0.06	(-1.58-1.45)	0.934
Week 4	2.60 (2.44)	3.60 (2.73)	-1.00	(-2.76-0.75)	0.254
Week 8	2.98 (2.68)	4.13 (3.35)	-1.16	(-3.21-0.90)	0.261
Week 12	2.98(3.13)	2.91 (3.00)	0.07	(-2.01-2.05)	0.945
Overall	-	-	-0.06	(-0.13-0.01)	0.073

Generalized estimating equation (GEE) statistics, Mean (SD), *$p < 0.05$ indicates statistical significance
MD, mean difference; CI, confidence interval
fESWT, focused extracorporeal shockwave therapy; TA, triamcinolone acetonide

Table 4. Comparison of the Thai version of the questionnaire assessing QDASH scores at baseline and at weeks 4, 8, and 12 after treatment

Follow-up session	fESWT group Mean (SD)	TA group Mean (SD)	MD	(95% CI)	*p-value
Baseline	19.00 (12.06)	20.57 (15.68)	-1.04	(-10.66-8.58)	0.827
Week 4	11.97 (11.63)	12.75 (12.67)	-1.50	(-9.74-6.74)	0.714
Week 8	18.76 (18.05)	17.88 (16.87)	-0.29	(-12.04-11.45)	0.959
Week 12	14.49 (14.84)	15.73 (20.83)	-2.74	(-14.70-9.22)	0.645
Overall	-	-	1.39	(-9.01-6.23)	0.720

Generalized estimating equation (GEE) statistics, Mean (SD), *$p < 0.05$ indicates statistical significance
MD, mean difference; CI, confidence interval
fESWT, focused extracorporeal shockwave therapy; TA, triamcinolone acetonide; QDASH, quick disabilities of the arm, shoulder and hand

Table 5. Comparison of the Thai version total BCTQ scores at the week before treatment and at weeks 4, 8, and 12 after treatment

Follow-up session	fESWT group Mean (SD)	TA group Mean (SD)	MD	(95% CI)	*p-value
Baseline	32.39 (8.21)	31.39 (8.82)	0.70	(-5.17-6.57)	0.809
Week 4	26.61 (10.43)	27.89 (9.24)	-2.09	(-8.61-4.42)	0.518
Week 8	28.89 (10.78)	31.28 (10.70)	-3.10	(-10.33-4.14)	0.390
Week 12	27.61 (8.68)	29.72 (12.21)	-2.96	(-9.99-4.05)	0.396
Overall	-	-	1.40	(1.21-1.60)	<0.001

Generalized estimating equation (GEE) statistics, Mean (SD), $^{*}p < 0.05$ indicates statistical significance
MD, mean difference; CI, confidence interval
fESWT, focused extracorporeal shockwave therapy; TA, triamcinolone acetonide; BCTQ, Boston Carpal Tunnel Questionnaire

Discussion

Our study showed a decrease in all parameters, but no statistically significant difference between the two treatment groups. The participants' outcomes were assessed at baseline and weeks 4, 8, and 12 after treatment, with the results shown in Tables 2-5. At the 4-week follow-up, both groups exhibited a reduction in VAS for pain, VAS for paresthesia, QDASH scores, and total BCTQ scores. However, the comparison between groups did not reveal any statistically significant differences (p = 0.987, 0.254, 0.230, 0.194). These findings suggest that while the treatments effectively reduced symptoms within each group, the improvement was comparable across groups. At the 8-week follow-up, there was a continued decrease in VAS for paresthesia, QDASH scores, and total BCTQ scores compared to baseline, except for VAS for pain in the fESWT group. Intriguingly, compared to the week 4 follow-up, an increase in these scores was observed, suggesting a potential fluctuation or plateau in symptomatic relief over time. However, comparisons between the groups showed no statistically significant differences (p = 0.482, 0.261, 0.959, 0.390), indicating that both groups experienced similar trends in symptom changes. By the 12-week follow-up, both groups had a notable reduction in VAS for pain, VAS for paresthesia, QDASH scores, and total BCTQ scores. Despite these improvements within each group, no statistically significant differences were identified between the groups (p = 0.300, 0.945, 0.645, 0.396). This consistent pattern of similar outcomes across both groups reinforces earlier findings that the treatment effects are equivalent throughout the study duration.

Overall, the data demonstrated a reduction in VAS for pain, VAS for paresthesia, QDASH scores, and total BCTQ scores from baseline to the 12-week follow-up in both groups. Although both groups benefited from the treatment, the lack of statistically significant differences between the groups (p = 0.107, 0.073, 0.720, < 0.001) indicates neither treatment regimen was superior. These findings suggest that the interventions provided comparable efficacy in managing symptoms in the study population. These results are consistent with Li et al.'s meta-analysis findings regarding pain relief and function improvement that the effects of ESWT and local corticosteroid injection for treating CTS are not significantly different.[19] The results are also consistent with the study by Vongvachvasin et al., which reported that fESWT combined with conservative treatment effectively improved symptoms and hand function in patients with moderate-to-severe carpal tunnel syndrome compared to conservative treatment alone.[20]

Seok et al. studied the effects of one session of ESWT for CTS and reported improvements in pain scores and functional status comparable to those achieved with local steroid injections.[13] Seok's study used ultrasonography to guide steroid injections and fESWT, yet the results were similar to those of the present study which did not utilize ultrasound guidance, a method not commonly used in Thailand. Additionally, a study by Gesslbauer suggested that fESWT is an effective and noninvasive treatment method for mild to moderate CTS.[21]

In our study, no side effects or serious complications occurred in the group treated with a single session of fESWT. However, one case of a side effect was reported after the steroid injection at the 4-week follow-up. This intervention involved a minor occurrence of nerve discomfort characterized by tingling and mild pain in the tip of the thumb. These symptoms resolved after appropriate treatment with medication.

Suggestions for future research projects include monitoring the duration of paresthesia symptoms returning after both treatments to assess treatment efficacy. Additionally, a cost-effectiveness comparison between the two treatments could be conducted to evaluate their relative value. This treatment employed single-session focused shockwave therapy which has shown lasting effects on patients for up to 12 weeks. However, further studies are needed to compare the effectiveness of single-session treatment versus weekly sessions to determine which approach yields superior outcomes.

Limitations of this research include the small number of participants which may be attributed to the limited diversity among research participants and the small sample size.

Conclusions

There is no evidence indicating a difference in clinical efficacy between single-session fESWT and steroid injection therapy in patients with moderate-degree carpal tunnel syndrome over a 12-week period. Therefore, noninvasive

fESWT can be considered an option to avoid possible side effects of steroid injection.

Acknowledgments

This study would not have been possible without the support and funding from the Faculty of Medicine, Srinakharinwirot University. We would like to express our gratitude to all the colleagues and participants at HRH Maha Chakri Sirindhorn Medical Center in Nakhon Nayok.

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