

Extracorporeal shock wave therapy versus corticosteroid injection in the treatment of trigger finger: a randomized controlled study

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Abstract

The purpose of this study was to compare the efficacies of extracorporeal shock wave therapy and corticosteroid injection for the management of trigger finger. In this prospective randomized clinical trial, 40 patients with actively correctable trigger fingers were randomly assigned to extracorporeal shock wave therapy (1000 impulses and 2.1 bar) or injection groups. The effectiveness of the treatment was assessed using cure rates, a visual analogue scale, the frequency of triggering, the severity of triggering, the functional impact of triggering, and the Quick-Disabilities of the Arm, Shoulder, and Hand questionnaire at 1, 3, and 6 months after treatment. An intention-to-treat analysis was used in this study. Both groups demonstrated statistically significant improvements in all outcome measures after treatment. The intention-to-treat analyses showed no between-group differences for cure rates, pain, and functional status at follow-up. We conclude that extracorporeal shock wave therapy could be a non-invasive option for treating trigger finger, especially for those patients who wish to avoid steroid injections.

Level of evidence: Level II.

Keywords

Trigger digits, stenosing tenosynovitis, injections, therapy, random allocation, intention to treat analysis

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Introduction

Trigger finger (also known as stenosing tenosynovitis) is a condition that causes triggering, snapping, or locking on flexion of the involved finger, with a lifetime risk between 2%–3% in the general population and approximately 10% in diabetic patients (Koh et al., 2010; Strom, 1997). A variety of treatments have been described, but the most effective treatment for this common disorder is still under debate.

Recently, extracorporeal shock wave therapy (ESWT) has been advanced as a possible alternative to surgery for the treatment of musculoskeletal disorders in patients recalcitrant to traditional conservative treatment. ESWT has been used to treat orthopaedic disorders, such as plantar fasciitis, lateral epicondylitis of the elbow, calcific tendinopathies of the shoulder, and the non-union of long bone fractures. It is believed to act by stimulating biological activities in cells, which results in a

mechanosensitive feedback between the acoustic impulse and the stimulated cells, involving specific transduction pathways and gene expression (Cacchio

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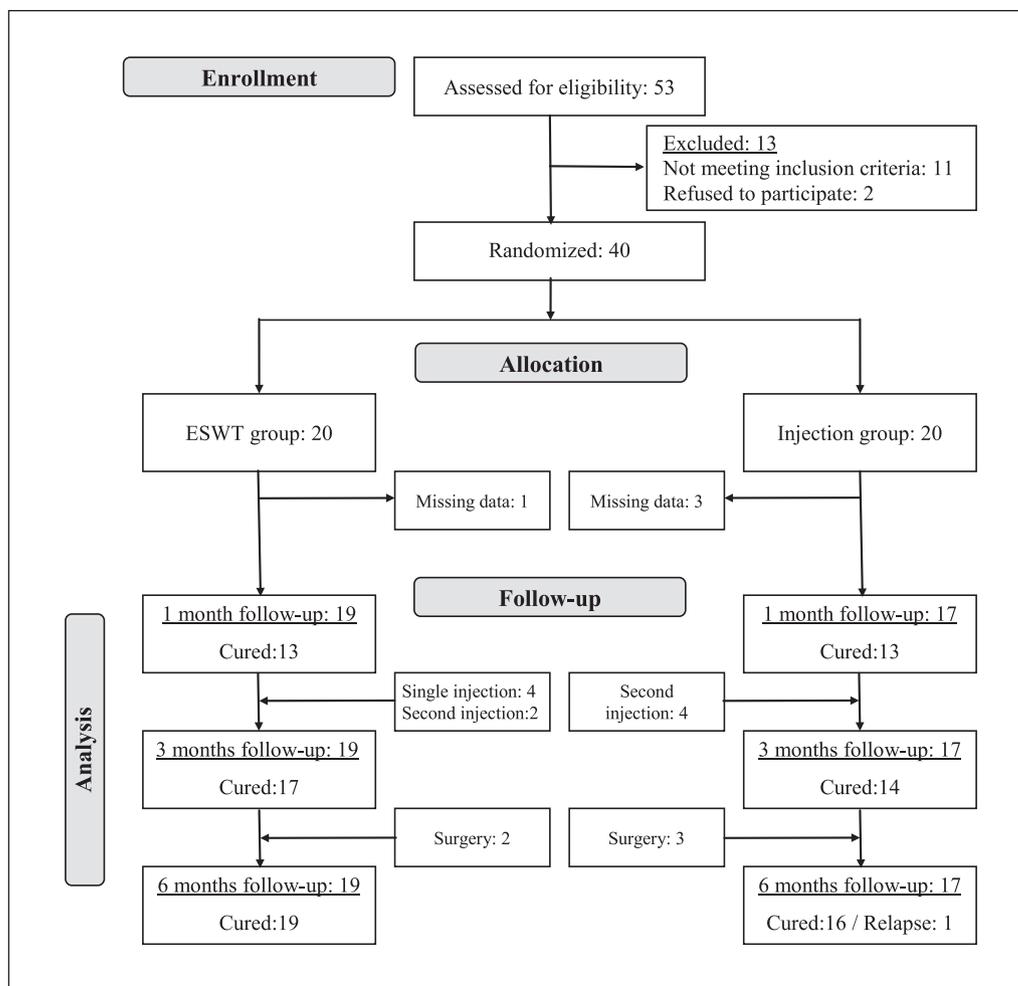


Figure 1. The flow of patients through the trial. ESWT: extracorporeal shock wave therapy.

et al., 2009; Mouzopoulos et al., 2007; Perez et al., 2003; Stasinopoulos and Johnson, 2005).

The aim of this study was two-fold: to determine the efficacy of ESWT in the treatment of trigger finger and to compare the efficacy of ESWT and a corticosteroid injection in the treatment of trigger finger.

Patients and methods

Study design

This was a prospective randomized controlled clinical trial with follow-up at 1, 3, and 6 months after treatment. Patients who signed informed consent were selected after receiving a comprehensive explanation of the research aims, benefits, and inherent risks, as well as the study procedure. The research protocol was reviewed and approved by the Clinical Research Ethics Committee of the university, and it was carried out in accordance with the principles of the Declaration of Helsinki.

Owing to a lack of data about the efficacy of ESWT in the treatment of trigger finger, the number of patients was determined based on the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire scores. Calculation of the sample size indicated that 34 patients were required (1:1 randomization, 17 per group) to allow 80% power to detect significance at the 5% level and a 25% group difference in DASH scores with a standard deviation (SD) of 25% (effect size: 1.0). We anticipated a ~20% dropout rate and started the study with 40 patients. The patients were randomized to the ESWT (20 patients) or injection group (20 patients) using the random number generation function in a commercially available software program (Microsoft Excel; Redmond, WA). Figure 1 shows the flowchart of the study.

Inclusion and exclusion criteria

Consecutive patients attending the outpatient clinic with a diagnosis of trigger finger between March

2013 and August 2014 were enrolled in the study. The diagnosis was based on the presence of tenderness over the A1 pulley and painful locking or triggering as the patient flexed and extended the digit.

Inclusion criteria were: patients older than 18 years of age and with grade 2 trigger finger based on the Quinell (1980) classification (grade 1, pretriggering; grade 2, actively correctable triggering; grade 3, passively correctable triggering; grade 4, uncorrectable locked finger). The exclusion criteria were: previous treatment by physical therapy, local corticosteroid injection, or surgical release for trigger finger before the study; the presence of a musculoskeletal disease or previous nerve injuries at the upper extremities; multiple trigger finger; local infection; malignancy; inflammatory arthritis; cardiac arrhythmia or cardiac pacemaker; and pregnancy.

Outcome measures

All the clinical outcomes were assessed before treatment and after 1, 3, and 6 months. Pain was measured using a visual analogue scale (VAS) ranging from 0 (no pain) to 10 (worst possible pain). Because of the lack of universally accepted instruments to measure frequency of triggering (FT), we used a 0- to 10-point trigger finger assessment scale to evaluate this parameter according to an earlier study (Tarbhai et al., 2012). This scale was also used to score the severity of triggering (ST) and the functional impact of triggering (FIT). The symptom severity and functional status of patients were measured using the Quick-Disabilities of the Arm, Shoulder, and Hand (QuickDASH) self-administered questionnaire (Beaton et al., 2001). The definition of cure rate was based on the Quinell classification. Patients classified as grade 0 (complete relief of triggering) were considered cured.

Intervention

All patients were asked to avoid repetitious movements of the hand and to apply a cold pack for 15 minutes each day, especially after repetitious movements.

Local corticosteroid injection. Under aseptic conditions, 0.5 mL of a betamethasone dipropionate/sodium phosphate solution and 0.5 mL of 2% lidocaine were injected into the A1 pulley from the palmar side using a 26-gauge needle, entering at the painful nodule; the angle of the needle during insertion was 45° distally. All injections were done by a rehabilitation physician who had extensive experience in corticosteroid injections in patients with trigger finger.

ESWT. A Vibrolith Ortho ESWT (Elopcomet GmbH, Roth, Germany) was used to administer the treatment of ESWT. The patient's hand was stabilized in a supine position on a table by the therapist. Each patient received 1000 shocks at an energy flux density of 2.1 bar (frequency 15 Hz) for three sessions (1-week interval between the sessions).

Statistical analysis

An intention-to-treat (ITT) analysis was carried out to assess the efficacy of the treatments. The ITT analysis included all patients who were initially randomized into one of the treatment groups and who received either three sessions of ESWT or a single corticosteroid injection. Based on the ITT principles, patients remained in the same group as at the beginning of the study, but were allowed to receive additional treatments, such as corticosteroid injection or surgery.

Means and frequencies were calculated for the demographic data and for the results of the subjective questionnaire analyses. For the demographics and clinical data of the patients, the Pearson Chi-squared test and Fisher exact tests were used for non-parametric data and Student's *t*-test was used for parametric data. The VAS, FT, ST, and FIT scores were compared between groups during the baseline, 1-, 3-, and 6-month assessments using the Student's *t*-test and within groups by paired Student's *t*-test. A post-hoc test (Bonferroni test) was used to compare means for the QuickDASH scores in an intragroup comparison of the baseline scores. An analysis of variance (ANOVA) was carried out to test differences in the QuickDASH scores between the groups at the baseline and at the 1-, 3-, and 6-month follow-ups. The Mann-Whitney *U*-test was applied to analyse differences between groups in terms of cure rates. Bonferroni test and ANOVA were used for parametric data; the Mann-Whitney *U*-test was used for non-parametric data. Statistical significance was set to $p \leq 0.05$.

Results

Of the original 40 patients, 36 patients completed the study (19 in the ESWT group; 17 in the injection group) (Figure 1). There was no significant difference between the two groups in terms of demographic data, including age, gender, and co-morbidities. The participants in the two groups also had similar baseline evaluation parameters (Tables 1 and 2).

One-month follow-up

Absence of triggering was documented in 13 of 19 patients in the ESWT group and in 13 of 17 patients in

Table 1. Demographics and clinical data of the patients.

	ESWT	CS injection	<i>p</i> -value
<i>Gender</i>			
Female/male	16/4	17/3	0.500 ^a
<i>Age, years</i>			
Mean (SD)	55 (8) (range 35–70)	54 (9) (range 37–67)	0.543 ^b
<i>Associated disease</i>			
CTS	3	2	0.456 ^c
DM	2	5	
CTS + DM	1	2	
Other	1	0	
<i>Family history</i>			
Positive/negative	4/16	3/17	0.500 ^a
<i>Duration in weeks*</i>			
Mean (SD)	10 (15) (range 1–52)	13 (13) (range 1–52)	0.309
<i>Hand dominancy</i>			
Right/left	19/1	17/3	0.534 ^a
<i>Affected digit</i>			
Thumb	15	12	0.615 ^c
Index	0	1	
Middle	1	2	
Ring	4	4	
Little	0	1	

CS: corticosteroid injection; CTS: carpal tunnel syndrome; DM: diabetes mellitus; ESWT: extracorporeal shock wave therapy.

^aFisher's exact test.

^bt-test.

^cPearson Chi-squared test.

the injection group. No statistically significant difference was found between the groups with regard to cure rates ($p=0.684$). In both groups, there were statistically significant differences between before and after treatment values in terms of all clinical assessments: VAS ($p<0.001$), FT ($p<0.001$), ST ($p<0.001$), FIT ($p<0.001$), and QuickDASH ($p<0.001$). When the groups were compared in terms of all the assessment parameters, there was no significant difference between the ESWT and the injection groups (all $p>0.05$) (Table 2).

Three- and 6-months follow-up

At the 3-month follow-up, the cure rates were 17 of 19 patients in the ESWT group and 14 of 17 patients in the injection group. After 1 month of follow-up, six patients in the ESWT group and four patients in the injection group received additional treatment according to the ITT analysis. In the ESWT group, six patients were given a corticosteroid injection and four of these six patients needed a second injection. In the injection group, four patients received a second injection. Eventually, at the 3-month follow-up, no statistically

significant difference was found when the groups were compared in terms of cure rate ($p=0.731$) and all clinical assessment parameters (all $p>0.05$) (Table 2). A second analysis was performed for patients who needed a corticosteroid injection in the ESWT group, and patients who were given a second corticosteroid injection in the injection group were considered to be failures of treatment at the 3-month follow-up. A significant difference was not observed between the groups in terms of the cure rate according to the second analysis ($p=0.684$).

After the 3-month follow-up, two patients in the ESWT group and three patients in the injection group continued to have symptoms and were advised to have surgical treatment. All the patients in the ESWT group and 16 patients of the injection group were assessed as asymptomatic at the 6-month follow-up. Clinical relapse was seen in one patient with obsessive-compulsive disorder in the injection group. No significant differences were found in terms of all the clinical assessment parameters (all $p>0.05$) (Table 2) and the cure rate ($p=0.778$) between groups. The patients who had surgical intervention were accepted as failures of treatment in both groups and a second analysis was done according to this statement. A significant difference was not observed between the groups with respect to this parameter according to the second analysis ($p=0.510$).

Compliance and adverse effects

Both interventions were well tolerated by most patients. One patient in the ESWT group and three patients in the injection group discontinued their participation in the study. There were no serious adverse events, such as infection or flexor tendon rupture, during the study period in either group.

Discussion

Our findings show that three sessions of ESWT treatment could be as effective as a corticosteroid injection for improving symptom severity and functional status in patients with a classification of grade 2 according to the Quinnell classification.

Currently, ESWT has been widely used in tendinopathies. Previous studies have shown that increased angiogenetic growth factors with ESWT are causally related to enhanced neovascularization and blood supply in the tendinopathic area of the tendon (Hsu et al., 2004; Orhan et al., 2004; Wang et al., 2003). It is also believed that ESWT induces the repair of the inflamed tissues by tissue regeneration and stimulates nitric oxide synthase, leading to suppression of ongoing inflammation in the soft tissues

Table 2. Functional and clinical data of the patients.

	ESWT			CS injection			ESWT vs CS injection
	Mean (SD)	Range	<i>p</i> ^{a,b}	Mean (SD)	Range	<i>p</i> ^{a,b}	<i>P</i> ^{c,d}
<i>VAS</i>							
Baseline	5 (1.8)	2–8		5.2 (1.8)	2–8		0.641
1 month	2 (2.7)	0–8	<0.001	1.3 (2.4)	0–7	<0.001	0.459
3 months	1 (2.5)	0–8	<0.001	0.8 (2.2)	0–7	<0.001	0.831
6 month	0.1 (0.4)	0–2	<0.001	0.4 (1.9)	0–8	<0.001	0.431
<i>FT</i>							
Baseline	9.3 (1.9)	2–10		9.7 (0.8)	8–10		0.446
1 month	3.5 (4.7)	0–10	<0.001	2.4 (4.4)	0–10	<0.001	0.430
3 months	1.1 (3.2)	0–10	<0.001	1.8 (3.9)	0–10	<0.001	0.466
6 months	0.0 (0.0)	0–0	<0.001	0.6 (2.4)	0–10	<0.001	0.551
<i>ST</i>							
Baseline	8.0 (0.0)	8–8		8.0 (0.0)	8–8		0.332
1 month	3.1 (3.9)	0–8	<0.001	1.9 (3.5)	0–8	<0.001	0.352
3 months	0.8 (2.5)	0–8	<0.001	1.4 (3.1)	0–8	<0.001	0.551
6 months	0.0 (0.0)	0–0	<0.001	0.5 (1.9)	0–8	<0.001	0.332
<i>FIT</i>							
Baseline	5.4 (2.5)	0–10		6.2 (1.8)	3–8		0.279
1 month	1.8 (2.5)	0–8	<0.001	1.4 (2.6)	0–6	<0.001	0.621
3 months	0.6 (1.9)	0–8	<0.001	1.1 (2.4)	0–6	<0.001	0.506
6 months	0.0 (0.0)	0–0	<0.001	0.5 (1.9)	0–8	<0.001	0.332
<i>QuickDASH</i>							
Baseline	46.3 (23.7)	4.6–90.9		40.2 (18.3)	2.3–65.9		0.401
1 month	15.8 (20.4)	0–70.5	0.001	13.6 (16.6)	0–50	0.001	0.732
3 months	5.0 (12.9)	0–52.3	<0.001	6.3 (14.7)	0–50	<0.001	0.785
6 months	1.7 (5.0)	0–15.9	<0.001	3.9 (16.0)	0–65.9	<0.001	0.572

CS: corticosteroid injection; ESWT: extracorporeal shock wave therapy; FIT: functional impact of triggering; FT: frequency of triggering; ST: severity of triggering; QuickDASH: Quick disabilities of the arm, shoulder and hand; VAS: visual analogue scale.

^aCompared with baseline (paired *t*-test).

^bQuickDASH values, compared with baseline (Bonferroni test).

^cTest values for the difference between ESWT and CS injection groups (independent *t*-test).

^dQuickDASH values for the difference between ESWT and CS injection groups (ANOVA).

(Ciampa et al., 2005; Seok and Kim, 2013). We are of the opinion that one of these mechanisms may also have a beneficial effect on the thickening of the flexor tendon and its sheath, resulting in overcoming the obstruction in the trigger finger.

Many factors can influence the effectiveness of ESWT in the treatment of tendinopathies. These include the location of pressure application, energy flux density, the total energy, the principle of shock-wave generation, and the device itself (Baloglu et al., 2005). Owing to the lack of evidence regarding its application for trigger finger, at the beginning of this study we decided to set 1000 shocks at an energy flux density of 2.1 bar by considering previous studies using ESWT in tendinopathies. We achieved high cure rates in the ESWT group using this setting; four of the six patients classified as failures of ESWT could not be successfully treated with an additional single corticosteroid injection.

One of the inclusion criteria in the current study was a diagnosis of grade 2 trigger finger. Patients with locking finger that was actively correctable were included in this study to ensure the precision of our results. Shinomiya et al. (2015) noted that corticosteroid injection was less effective in trigger finger with proximal interphalangeal joint flexion contracture compared with those without contracture. Salim et al. (2012) investigated the effectiveness of physiotherapy and corticosteroid injection in patients with mild trigger finger. Their study showed high (97%) and moderate (69%) success rates with corticosteroid injection and physiotherapy, respectively. We are of the opinion that they achieved a higher than expected cure rate with a corticosteroid injection because of their inclusion criteria, which specified not only patients with trigger finger grade 2, but also patients with mild crepitus and uneven finger movements.

The results of our study are consistent with several previous reports comparing corticosteroid injection and ESWT in tendinopathies (Kim et al., 2014; Lee et al., 2012; Mani-Babu et al., 2015). However, Crowther et al. (2002) compared the analgesic effects of ESWT and corticosteroid injection in the treatment of tennis elbow using a reduction in pain of 50% as a criterion of treatment success at 3-months follow-up. They concluded that both treatments relieve symptoms, but a corticosteroid injection was more effective than ESWT. In addition, they emphasized that the differences in the cost-effectiveness of the treatments favoured corticosteroid injection. Although we agree with this point, we recommend ESWT for patients who reject corticosteroid injections because of their potential complications, or who are allergic to local anaesthetics, as well as in patients with an intense and persistent fear of injections ('needle phobia') (Akhtar et al., 2005). Even though no deleterious effect of corticosteroid injection was seen in the current study, there have been previous reports of dermal or subcutaneous atrophy, transient hyperglycaemia, hypopigmentation of the skin, infection, and rupture of the flexor digitorum profundus tendon in rare cases (Akhtar et al., 2005; Hamano et al. 2013; Makkouk et al., 2008; Oh et al., 2015).

The present study does have some limitations, primarily the lack of a third placebo control group. We did not think it was ethical to withhold treatment from patients with pain and hand disability during the 6-month study period. Thus, we used an ITT analysis comparing ESWT and corticosteroid injection to apply optimal treatment strategies in those patients. Because there was no current evidence regarding the use of ESWT for the management of trigger finger, we allowed patients to receive two corticosteroid injections or surgery if needed after being assessed at the 1-month follow-up and 3-month follow-up, respectively. It has been accepted that ITT analysis is a better reflection of the effectiveness of treatment in clinical practice. Moreover, we performed a second analysis considering an additional intervention as a failure at the 3- and 6-month follow-ups to eliminate the effect of additional treatments. Another limitation of the study is that the pain from the procedures was not scored or compared between the groups. Nevertheless, we carefully chose patients with grade 2 trigger finger and compared the potentially effective treatment modality (ESWT) and a well-known treatment approach (steroid injection) using the outcomes of symptom severity and cure rates.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

The research protocol was reviewed and approved by the Clinical Research Ethics Committee of Kocaeli University with registration No. KOU-KAEK 2013/62

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