

Effect of Corticosteroids on Pain and Function in Patients with Tennis Elbow Compared to Normal Saline: A Triple-Blind Randomized Clinical Trial

Abstract

Introduction: Tennis elbow or lateral epicondylitis is usually associated with chronic disability, and to date, a suitable and effective treatment has not been introduced. Therefore, finding a treatment for this condition is essential aim of this study to investigate the effect of corticosteroids on pain and function in patients with tennis elbow.

Materials and Methods: This study was conducted on 43 patients (21 injected with normal saline and 22 with the corticosteroid). Patients were randomly assigned to two groups, and the prescribed medications were administered. Pain and function in patients were recorded 1 month and 3 months later. Chi-square tests and Mann-Whitney tests were used to compare the data.

Findings: The results of our study showed that both treatment methods, corticosteroid injection and normal saline, resulted in short-term improvement of pain and function in patients based on the DASH questionnaire ($p < 0.05$). However, in the long term (3 months after intervention), similar to normal saline, we observed a recurrence of symptoms, with pain scores increasing by 0.5 to 1 unit and DASH scores increasing by 5 to 10 units.

Conclusion: It can be concluded that corticosteroid injection does not have superiority over normal saline, and both methods have a minor effect in the long term and are more effective in the short term. Given the high side effects of corticosteroids, treatment with normal saline is preferred.

Keywords: Lateral epicondylitis, corticosteroids, normal saline

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Introduction

Tennis elbow (Elbow tennis) or lateral epicondylitis (Epicondylitis lateral) is the most common cause of elbow pain, usually felt on the outer part of the elbow. This condition involves the muscles, tendons, and epicondyle (a bony prominence on the outer surface of the elbow that serves as the attachment site for some forearm muscles). The pathophysiology of lateral epicondylitis typically involves the osteotendinosis of the wrist extensor muscles at their origin (the lateral epicondyle). Among them, the extensor carpi radialis brevis tendon is most commonly affected⁽¹⁻³⁾. Tennis elbow is often seen in adults over 30 years old who engage in tennis regularly, as well as mechanics and carpenters. Symptoms include pain and tenderness at the epicondyle, weak fist and pain when clenching, pain during twisting movements of the hand or arm, such as using a screwdriver or playing tennis. Notably, no specific findings are observed on radiographs of these individuals^(1, 4).

Various studies have been conducted regarding tennis elbow and its treatment methods. These studies have reported various treatment methods, including hot or cold compresses, local physiotherapy, immobilization and hanging the affected arm for 3 to 8 weeks depending on the severity of the condition, and reducing hand activity for one month. The use of non-steroidal anti-inflammatory drugs such as ibuprofen, naproxen, etc., as well as local injections of cortisone (corticosteroids) or anesthetics at the affected site, are other treatment and intervention methods^(5, 6). If no improvement is achieved after 6 to 12 months of these measures, surgery may assist the patient. Surgery typically involves releasing the attachment site of the forearm extensor muscles from the lateral epicondyle and sometimes releasing the deep branch of the radial nerve in the elbow region. Surgery can be performed either openly or arthroscopically⁽⁷⁻⁹⁾.

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One treatment method is the use of corticosteroids, with some studies confirming the positive therapeutic effect of corticosteroids, while others refute this hypothesis. Steroid injections to the area around the elbow with the highest local tenderness are among the most common treatments for this resistant non-invasive condition⁽¹⁰⁾. Reports indicate that these injections can be helpful in 90% of patients for less than one year, although these invasive methods can be very harmful (local side effects include flare-ups post-injection, hypopigmentation and skin atrophy, infection, tendon rupture, accelerated osteoarthritis progression, and bone damage. Systemic side effects include adrenal suppression or failure, facial flushing, hypertension, hyperglycemia, and osteoporosis). They also have a high rate of complications and recurrence. In some studies, the success rate of this treatment method has been reported as low as 5%, indicating a significant contradiction in the studies⁽⁹⁻¹³⁾.

Despite research conducted on the beneficial effects of steroid injections in patients with lateral epicondylitis, studies on this topic are limited and present contradictory results regarding the success rate of this treatment method. Additionally, living in areas with low annual family incomes and economic difficulties, along with the lack of effective treatment, imposes exorbitant costs on families. Given the significant side effects of invasive steroid injections, there is a need to find a more suitable treatment method to alleviate patients' pain when steroids are ineffective. Therefore, the aim of this study is to investigate the effect of corticosteroids on pain and function in patients with tennis elbow.

Methods

This study is a clinical trial registered with code IR.AJAUMS.REC.1397.016 at the Iranian Clinical Trials Center. The study was conducted in 1397 (2018) on patients with lateral epicondylitis who had been diagnosed for at least three months and visited the outpatient clinic of the 501 Army Hospital. After entering the study and obtaining consent, all patients (control and intervention groups) underwent diagnostic and treatment measures based on the decision of the responsible physician upon entering the study. Inclusion criteria for the study included the presence of pain in the outer elbow based on at least 2 out of 4 tests: localized

pressure, resisted wrist extension, resisted middle finger extension, and resisted finger extension (2 to 5). The duration of symptoms should be at least 6 weeks. In complicated cases, Electromyogram-Nerve conduction velocity was used as part of the diagnostic process for patients. Patients with localized elbow arthritis (clinically or radiologically diagnosed), generalized polyarthritis, neurological abnormalities in the arm, a history of steroid injections or any local treatment in the past month, closed epiphyses, pregnancy, or systemic diseases were excluded from the study. This study is a triple-blind randomized clinical trial. All patients who met the inclusion criteria were considered for enrollment. After obtaining written consent and explaining the study conditions, patients were asked to complete a demographic information questionnaire, including age, gender, body mass index (BMI), occupation, duration of pain, and diagnosis of the disease. Patients were then asked to rate their pain levels based on a Visual Analog Scale (VAS), and each participant completed the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire. They were then randomly assigned to one of the study groups. The first group received triamcinolone (in the form of a 2 cc ampule of triamcinolone 40 mg/ml, manufactured by Daro Pakhsh Company, Tehran, Iran) and the second group received normal saline injection (manufactured by Caspian Pharmaceutical Company, Rasht, Iran). Both groups also received physiotherapy treatment.

After signing the informed consent form, patients were randomly and using a sealed envelope method assigned to either the treatment or control group. Both groups underwent specific strengthening and stretching exercises for lateral epicondylitis progressively. The treatment group received corticosteroids in addition to the exercises, while the control group received a placebo. Patients were clinically evaluated before treatment, after one month, and after three months of treatment, and the results were recorded in pre-prepared forms.

All patient information, including demographic factors and paraclinical symptoms, was recorded on a checklist created by the investigator and entered into the SPSS software (IBM Corporation, Armonk, NY, version 22). Statistical analyses were performed in both descriptive and analytical sections. In the descriptive section, the mean and standard deviation of pain and function as the main variable

were presented across different groups, and all demographic and clinical characteristics of patients were reported based on descriptive criteria. In the analytical section, based on the fulfillment of statistical assumptions, parametric and non-parametric tests were used. For analyzing qualitative findings, the Chi-square test was used, and for comparing quantitative data, the independent T-test was used. If initial assumptions such as normality were not met, the Mann-Whitney U test was employed. All tests were examined at a significance level of 5%. To assess changes in outcome measures, repeated measure ANOVA (FFT) and post hoc tests were conducted.

Findings

The present study aimed to investigate the effect of corticosteroids on pain and function in patients with tennis elbow compared to the effect of normal saline on pain and function in the same patient group. In this study, 50 patients were enrolled (25 in each group), with 7 patients excluded during the follow-up. Ultimately, 21 patients in the normal saline group and 22 patients in the corticosteroid group were analyzed (Figure 1). Among the 43 enrolled patients, 20 (46.5%) were male, and 23 (53.5%) were female. The mean age of the participants was 40.27 years (± 9.11), ranging from 22 to 57 years (Table 1).

Fig.1: Study Flowchart (CONSORT format)

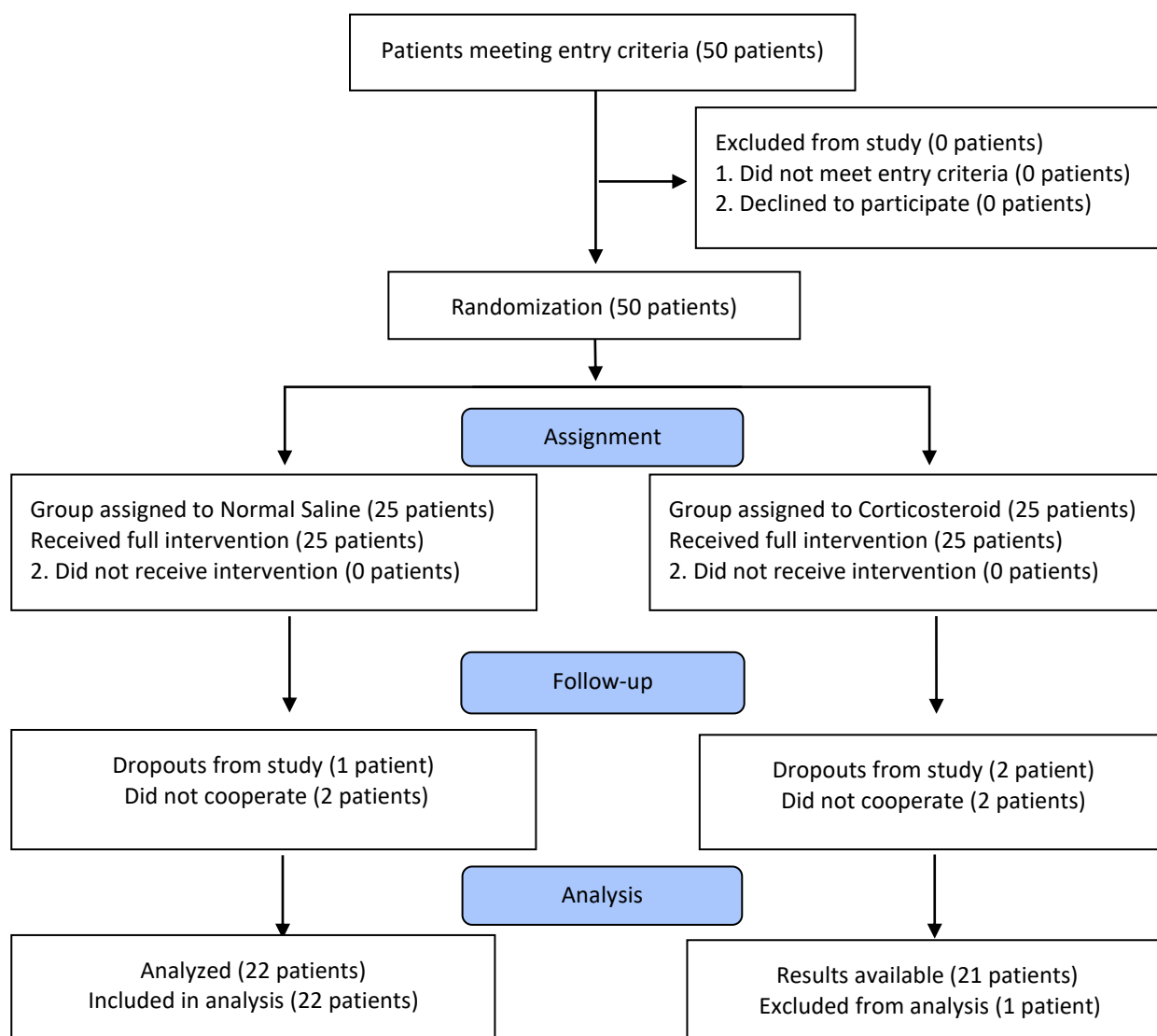


Table 1. Demographic and Clinical Information of the Studied Patients

Group	Normal Saline	Corticosteroid	Total	P-value
Dominant Hand				
Non-dominant	Count	5	5	10
	Percentage	23.8%	22.7%	23.3%
Dominant	Count	16	17	33
	Percentage	76.2%	77.3%	76.7%
Occupation				
Housewife	Count	6	5	11
	Percentage	28.6%	22.7%	25.6%
Employee	Count	7	6	13
	Percentage	33.3%	27.3%	30.2%
Laborer	Count	5	8	13
	Percentage	23.8%	36.4%	30.2%
Freelance	Count	2	1	3
	Percentage	9.5%	4.5%	7.0%
Athlete	Count	1	2	3
	Percentage	4.8%	9.1%	7.0%
Duration of Illness (weeks)				0.742
	Count	21	22	43
	Mean \pm SD	19.9 \pm 6.9	19.6 \pm 9.0	19.5 \pm 8.4
Body Mass Index (BMI) (kg/m ²)				0.497
	Count	21	22	43
	Mean \pm SD	25.2 \pm 2.5	25.6 \pm 2.4	25.3 \pm 2.6
Gender				0.887
Male	Count	10	10	20
	Percentage	47.6%	45.5%	46.5%
Female	Count	11	12	23
	Percentage	52.4%	54.5%	53.5%
Age				0.556
	Count	21	22	43
	Mean \pm SD	39.4 \pm 10.1	41.9 \pm 7.5	40.3 \pm 11.9

As shown in the above table, there were no statistically significant differences in mean age, BMI, duration of illness, gender distribution, occupation, and dominant hand between the two study groups ($P > 0.05$).

According to Table 2, in our study, no significant differences were observed in pain during lifting, pain

when twisting, pain during daily activities, pain during middle finger extension, pain during extension of fingers 2 to 5, pain during wrist extension, DASH score, tenderness to palpation, and satisfaction score between the two patient groups at baseline, 1 month, and 3 months after treatment ($P > 0.05$).

Table 2. Comparison of the Effect of Corticosteroid Injection vs. Normal Saline on Pain Levels in Patients with Tennis Elbow

Variable	Time	Before Treatment	One Month After Treatment	Three Months After Treatment
Pain during lift	Normal Saline (n=21)	7.42 ± 1.24	3.95 ± 1.49	4.23 ± 1.26
	Corticosteroid (n=22)	7.27 ± 1.77	3.86 ± 1.72	4.36 ± 1.29
	P-value	0.870	0.678	0.735
Pain during twisting	Normal Saline (n=21)	7.19 ± 1.07	4.09 ± 1.48	4.52 ± 1.16
	Corticosteroid (n=22)	7.27 ± 1.24	3.86 ± 1.72	4.45 ± 1.26
	P-value	0.712	0.472	0.871
Pain during daily activities	Normal Saline (n=21)	7.33 ± 1.46	3.57 ± 1.43	4.42 ± 0.92
	Corticosteroid (n=22)	7.63 ± 1.21	3.54 ± 1.81	4.72 ± 1.02
	P-value	0.560	0.522	0.342
Pain during middle finger extension	Normal Saline (n=21)	6.14 ± 1.31	3.78 ± 1.78	3.47 ± 1.47
	Corticosteroid (n=22)	6.50 ± 1.62	2.19 ± 2.15	3.63 ± 1.59
	P-value	0.443	0.501	0.707
Pain during extension of fingers 2 to 5	Normal Saline (n=21)	6.23 ± 1.61	3.47 ± 1.32	3.57 ± 1.53
	Corticosteroid (n=22)	6.27 ± 1.88	3.02 ± 2.00	3.63 ± 1.59
	P-value	0.951	0.060	0.812
Pain during wrist extension	Normal Saline (n=21)	7.09 ± 1.48	3.09 ± 1.06	4.41 ± 1.41
	Corticosteroid (n=22)	7.13 ± 1.28	3.86 ± 1.72	4.73 ± 1.54
	P-value	0.890	0.795	0.321
DASH Score	Normal Saline (n=21)	42.04 ± 10.44	23.28 ± 8.31	28.14 ± 5.41
	Corticosteroid (n=22)	41.41 ± 8.77	24.09 ± 9.91	29.81 ± 5.94
	P-value	0.535	0.942	0.323
Sensitivity to touch	Normal Saline (n=21)	90.5% (19)	23.8% (5)	33.3% (7)
	Corticosteroid (n=22)	90.9% (20)	27.3% (6)	36.4% (8)
	P-value	0.961	0.795	0.835
Satisfaction Score	Normal Saline (n=21)	3.14 ± 0.96		
	Corticosteroid (n=22)	3.27 ± 0.98		
	P-value	0.683		

Discussion

The present study aimed to investigate the effect of corticosteroids on pain and function in patients with tennis elbow compared to the effect of normal saline on pain and function in patients with tennis elbow. According to the results of this study, there was no statistically significant difference between the two groups regarding pain, performance scores, sensitivity to touch, and ultimately satisfaction between the two groups.

In 2015, Lebedziniki et al. conducted a study⁽¹⁴⁾ that aimed to evaluate the effect of autologous conditioned plasma (ACP) injection compared to corticosteroid injection (Betamethasone) over a one-year follow-up. The study method involved randomly assigning patients to one of two groups, both of which were comparable based on the initial DASH score. Fifty-three patients were treated with ACP, and 46 others received treatment with 1 ml of Betamethasone and 2 ml of 1% Lidocaine. After six weeks, the DASH scores in the Betamethasone treatment group were significantly better, indicating improvement; however, after one year, the ACP-treated group had improved, with complete recovery being more prevalent in the Betamethasone group. Nevertheless, after one year, the comparison of DASH scores in both groups showed that the ACP group received very good and good results, while the pain symptoms in the ACP group were greater than those in the Betamethasone group. Our study also indicated that corticosteroid injection significantly reduced pain and DASH scores in patients within one month, but this reduction was also observed in the normal saline group. In other words, the effect of corticosteroid injection is similar to that of normal saline.

In 2015, Murtezani A et al.⁽¹⁵⁾ evaluated the efficacy of corticosteroid injection and physiotherapeutic interventions (ultrasound and exercise) in treating chronic cases of these patients in a clinical trial involving 49 patients. The results indicated the usefulness of treatment with ultrasound and exercise for these patients⁽¹⁶⁾. However, our study found that corticosteroid injection significantly reduced pain and DASH scores and also led to a significant reduction in the frequency of sensitivity to touch in patients in the first month after injection. However, after three months, it was observed that pain and DASH scores were increasing. These

findings were also observed in the normal saline group.

In a study conducted in Turkey in 2010 by Ozturan et al.⁽¹⁶⁾, the aim was to compare the effects of autologous blood injection, corticosteroid injection, and shockwave therapy in treating lateral epicondylitis. Sixty individuals (32 women and 28 men) were randomly divided into three groups: corticosteroid injection (group one), autologous blood injection (group two), and shockwave therapy (group three). The results were evaluated at 4, 12, 26, and 52 weeks post-treatment. In the fourth week, the corticosteroid injection showed significantly better results compared to the other treatment methods according to the stated criteria. The success rates in the fourth week among the three groups were 90%, 16.6%, and 42.1%, respectively. However, in the fifty-second week, autologous blood injection and shockwave therapy showed better results in the Thomson test and upper extremity functional score. In the fifty-second week, the success rate for corticosteroids was 5%, while for autologous blood injection, it was 83%, and for shockwave therapy, it was 89%.

In our study, it was also found that corticosteroid injection had a favorable effect on both pain and function, significantly reducing pain and improving patient function in the first month after treatment, but in the long term, a partial return in the scores of both variables was observed. These effects were also noted regarding normal saline injection. The findings regarding the ineffectiveness of corticosteroid injection on function oppose the results obtained from our study, and the reason for this discrepancy may be due to differences in sample size, duration of patient follow-up, demographic differences among patients, differences in inclusion and exclusion criteria, and differences in sampling methods.

In 2011, a study comparing autologous blood injection, corticosteroids, and normal saline in treating lateral epicondylitis was conducted on 28 individuals over a duration of less than six months. Patients were followed up six months post-injection, and the results indicated reductions in DASH scores, functional scores, and pain. They were given stretching exercises, and the measurements were at an acceptable level. All three injections resulted in reductions in DASH scores at 2 weeks and 2 months and a significant reduction at 6 months; however, there were no significant differences among the

three groups. Additionally, patients reported improvements in pain and function scores across all three groups⁽¹⁷⁾. However, our study indicated that both treatment methods, corticosteroid injection and normal saline, resulted in short-term improvements in pain and function based on the DASH questionnaire but saw a return of symptoms in the long term (3 months later) similar to normal saline, with pain scores increasing by 0.5 to 1 unit and DASH scores increasing by 5 to 10 units. Therefore, it can be concluded that corticosteroid injection does not have an advantage over normal saline, and both methods are ineffective for long-term impact, being more effective in the short term, requiring other methods for ongoing improvement in patients.

In a study by Krogh et al.⁽¹⁸⁾ in 2013 aimed at evaluating corticosteroid injection compared to normal saline in improving lateral epicondylitis, it was shown that steroids were more effective in reducing pain at one month compared to saline or platelet-rich plasma injections, but at three months, there was no specific method with a particular advantage. Additionally, it was shown that corticosteroid injection resulted in reduced color Doppler activity and tendon thickness compared to other conditions, placing patients at greater risk for side effects. Thus, considering the results of our study and the aforementioned study and the equivalent therapeutic effects of normal saline with corticosteroid injection, alongside the occurrence of side effects in the corticosteroid injection group, it can be concluded that the best treatment method between corticosteroid injection and normal saline is normal saline, which has limited side effects.

Corticosteroid injection also has several adverse effects, the most serious of which is tendon rupture. These adverse effects have been reported in many clinical studies assessing the efficacy of corticosteroid injection. It seems there are adverse effects for all injection methods except for platelet-rich plasma and sclerosing agents⁽¹⁹⁾. Therefore, exploring other methods, including platelet-rich plasma and sclerosing agents compared to normal saline, in future studies is essential to arrive at the best treatment method for these patients.

Conclusion

In conclusion, our study indicated that both corticosteroid injection and normal saline result in

short-term improvement of pain and function in patients based on the DASH questionnaire ($p < 0.05$). However, in the long term (3 months after intervention), we observed a recurrence of symptoms, similar to normal saline. Based on the high side effects of corticosteroids, treatment with normal saline is preferable, and future studies should focus on more effective and less invasive treatment methods.

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