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The effect of corticosteroid, and saline injection on pain perception and function of patients with lateral epicondylitis: A triple-blinded, randomized, controlled trial

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ABSTRACT

Introduction: Lateral epicondylitis is usually associated with chronic disability and no suitable treatment is available for it. Investigating effective treatment methods for this disease is essential. We compared saline, corticosteroid for lateral epicondylitis in a triple-blinded, randomized, controlled trial.

Materials and methods: Patients with clinically diagnosed lateral epicondylitis of less than 3 months' duration were included in the study. First, demographic information was completed for each patient. Then the patients were asked to rate their pain level based on the VAS scale and the DASH performance questionnaire was also completed for each person. Then, the first group was treated with triamcinolone and the second group was treated with normal saline injection. Patients underwent clinical evaluation before and after one month and after three months of treatment.

Results: Our findings demonstrated that both corticosteroid injection and normal saline treatment were capable of improving the pain and function of the patients in terms of the DASH questionnaire in the short term, but similar to normal saline, symptoms returned in the long term (after 3 months), where the pain score increased between 0.5 and 1 units and the DASH score increased between 5 and 10 units.

Conclusion: Corticosteroid injection was not found to be superior to saline, when both methods were ineffective in terms of long-term effects, while they were more effective in the short term.

Keywords: *External epicondylitis, corticosteroid, normal saline*

INTRODUCTION

Lateral epicondylitis (tennis elbow) is usually associated with chronic disability. The wrist extensor tendons, especially the extensor carpi radialis brevis, are contracted at the point of their attachment to the external external epicondyle of the arm to keep the wrist stable in the extend position, which is caused by a series of repetitive activities specific to sports or work, such as working with a computer, weight lifting, gardening, and playing tennis, leading to stretching, pain and inflammation (1-3). Although this lesion is completely extra-articular, if it persists, it can also involve joint structures such as the joint synovial membrane, the upper end of the ulna and radius, and the annular ligament (4, 5).

There are several recommendations for conservative and surgical treatment, including ultrasound, short-wave diathermy, acupuncture, immobilization, local steroid injection, and various surgical procedures. External epicondylitis usually occurs as a result of increased activity of the Extensor digitorum communis (EDC) tendons of the wrist or fingers, which can be related to work or sports. A gap on the extensor tendon of the external epicondyle and the subsequent periosteum, as well as macroscopic and microscopic gaps have been found in patients who need surgery. Infiltration of immature and vascular fibroblasts have also been reported. The tendon junction is relatively avascular and its poor recovery is probably related to ischemia in that position (6).

The necessity of treatment comes from the fact that the use of treatment improves not only the pain of the patients but also improve its associated life problems, unfortunately, despite the fact that more than 40 different types of treatment have been identified for this disease. So far, there is no consensus on the most appropriate treatment. The standard treatment for tennis elbow is to use non-invasive methods (7-9). Steroid injection to the area around the elbow with the greatest local sensitivity is one of the most common treatments for this disease resistant to non-invasive treatment. Reports indicate that these injections can help less than a year in 90% of patients (10).

Although these methods are invasive, they can be very harmful, when may be associated with high complications and recurrence. On the other hand, the success rate of this treatment method has been reported up to 5% in some studies, indicating a strong contradiction in studies (11-13).

Investigating the beneficial effects of steroid injection on the pain of patients with lateral epicondylitis is of great importance for replacing a more appropriate treatment method in treatment of patients suffering from tennis elbow. Therefore, the current study aimed at investigating the effect of corticosteroids on the pain and performance of patients with tennis elbow.

MATERIALS AND METHODS

Patients with diagnosed lateral epicondylitis of less than 3 months' duration were included in the study. Patients. Inclusion criteria include: presence of elbow pain in at least 2 out of 4 local pressure tests, resistance extension of the wrist, middle finger, and fingers 2 to 5, as well as duration of symptoms of at least 6 weeks.

Exclusion criteria include: local elbow arthritis, generalized polyarthritis, neurologic abnormality in the arm, steroid injection or any local treatment in the past month, closure of the epiphyseal plate, pregnancy, systemic disease, lack of consent to enter the study, patient loss in 3-month follow-up, having symptoms for less than 3 months, history of elbow trauma, history of connective tissue disease or diffuse pain syndrome (such as fibromyalgia, chronic pain syndrome), presence of inflammatory arthropathy, use of previous treatments for lateral epicondylitis, presence of radiculopathy, complete rupture of extensor carpi radialis brevis (ECRB) tendons, effusion in the elbow area, use of anticoagulant drugs and the presence of contraindications for injection and physiotherapy.

Sample size

According to Bisset's study (14), d (31.9), power (80%) and difference coefficient (10%) were considered. (α=0.05, β=0.2). 12 patients were calculated for each group, and the sample size was considered to be 20 patients in each group to increase accuracy.

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (SD_1^2 + SD_2^2)}{d^2}$$

Procedure

At first, demographic information including age, sex, BMI, occupation, duration of pain and disease diagnosis was completed for each patient. Then, the patients were asked to rate their pain level based on the VAS scale, and the DASH performance questionnaire (15) was also completed for each person. Then they were randomly assigned to each of the studied groups. The first group was treated with triamcinolone (40 mg/ml, manufactured by Daru Pasha, Tehran, Iran) and the second group was treated with normal saline injection (Caspin Daru, Rasht, Iran). Also, both groups were treated with physiotherapy.

Then, they were randomly divided into two treatment and control groups using the closed

head envelope method. Both groups underwent strengthening and stretching exercises for lateral epicondylitis in a progressive manner. The treatment group received corticosteroids in addition to exercises and the control group received Placid. Patients underwent clinical evaluation before and after one month and after three months of treatment.

Data analysis

Statistical analyzes were presented in two descriptive and analytical sections. In the descriptive part, the mean and standard deviation of pain and function were presented as the main variables in different groups. In the analytical part, parametric and non-parametric proportional tests were used. Chi-square test was used to analyze qualitative findings and independent T-test was used to compare quantitative data. If the initial assumptions such as normality were not met, Mann-Whitney parametric bread was used. All tests were analyzed at the 5% error level. FFTCpeated measure ANOVA and post hoc tests were used to examine the changes in outcome measures. All analyzes were done using SPSS software version 22.

Ethics declarations

A written letter of introduction was received from the respected officials of the university for introduction to the research centers. A written letter of introduction was obtained from the respected officials of the selected research centers. The purpose of the study was explained to all research units and written consent was obtained from them. The information of all patients will be kept confidential with the project manager. All methods were carried out in accordance with declarations of Helsinki and ethics research committees of the University of Medical Sciences. The project was carried out after being approved by the Research Council of the Faculty of Medicine (number :….).

RESULTS

A total of 50 patients were included in the study, of which 7 patients were withdrawn during the study. Finally, 21 people in the normal saline group and 22 people in the corticosteroid group were analyzed, of which 20 people (46.5%) were men and 23 people (53.5%) were women. The average age of the subjects studied was 40.27 ± 9.11 years (22-57 years). The average of covid-19 infection in the normal saline group and the other group was 6.81±19.09 and 9.46±19.86, respectively (=0.742 g).

Frequency of gender, occupation and dominant hand in patients of two groups did not show statistically significant difference (P>0.05; Figure 1).

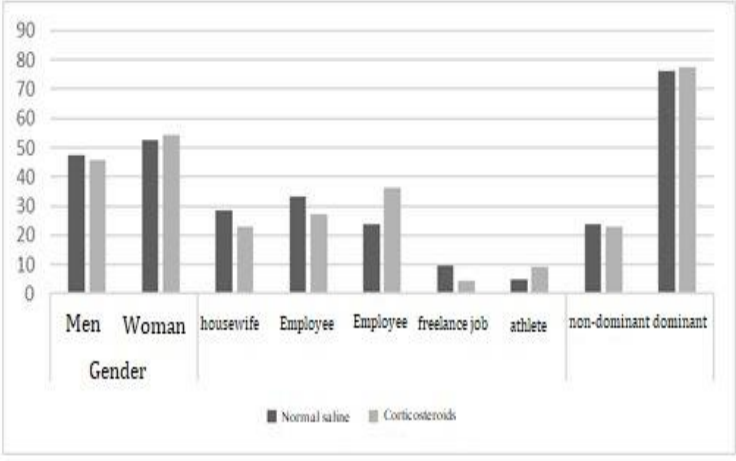

FIGURE 1: Frequency of gender, occupation and dominant hand in patients of two studied groups

Table 1 shows the average pain during Lift, Twist and performing daily activities in the two groups of patients where there was no statistically significant difference in the patients of the two groups (P>0.05).

TABLE 1: Mean and standard deviation of pain during lift, twist and daily activities

Time	Group	Number	Mean	SD	P-value
before treatment	normal saline	21	7.42	1.24	0.87
	Corticosteroids	22	7.27	1.77	
One month after treatment	normal saline	21	3.95	1.49	0.678
	Corticosteroids	22	3.86	1.72	
Three months after treatment	normal saline	21	4.23	1.26	0.735
	Corticosteroids	22	4.36	1.29	
	group Twist				
before treatment	normal saline	21	7.19	1.07	0.712
	Corticosteroids	22	7.27	1.24	
One month after treatment	normal saline	21	4.09	1.48	0.472
	Corticosteroids	22	3.86	1.78	
Three months after treatment	normal saline	21	4.52	1.16	0.871
	Corticosteroids	22	4.45	1.26	
Tie	Daily activity group				
before treatment	normal saline	21	7.33	1.46	0.56
	Corticosteroids	22	7.63	1.21	
One month after treatment	normal saline	21	3.57	1.43	0.522
	Corticosteroids	22	3.54	1.81	
Three months after treatment	normal saline	21	4.42	.92	0.342
	Corticosteroids	22	4.72	1.2	

The average pain (Table 2) during extension of middle finger, 5th to 2nd finger and wrist was not statistically significant (P>0.05).

TABLE 2: Average pain during extension of middle finger, extension of 5th to 2nd finger and wrist

Time	Group	Number	Mean	SD	P-value
Before middle finger extension treatment	normal saline	21	6.14	1.31	0.443
	Corticosteroids	22	6.5	1.62	
One month after treatment	normal saline	21	3	1.78	0.501
	Corticosteroids	22	2.9	2.15	
Three months after treatment	normal saline	21	3.47	1.6	0.707
	Corticosteroids	22	3.63	1.59	
	Finger extension group 2 to 5				
before treatment	normal saline	21	6.23	1.6	0.951
	Corticosteroids	22	6.27	1.88	
One month after treatment	normal saline	21	3.47	1.32	0.06
	Corticosteroids	22	3	2.02	
Three months after treatment	normal saline	21	3.57	1.53	0.812
	Corticosteroids	22	3.63	1.39	
	Wrist extension group				
before treatment	normal saline	21	7.09	1.48	0.89
	Corticosteroids	22	7.13	1.28	
One month after treatment	normal saline	21	3.9	1.6	0.795
	Corticosteroids	22	3.86	1.72	
Three months after treatment	normal saline	21	4	1.41	0.321
	Corticosteroids	22	4.5	1.73	

As shown in Table 3, the mean and standard deviation of the DASH score in the patients of the two study groups had no statistically significant difference (P>0.05).

TABLE 3: Mean and standard deviation of DASH score

Time	group	number	mean	SD	P-value
before treatment	normal saline	21	42.04	10.44	0.535
	Corticosteroids	22	41.5	8.77	
One month after treatment	normal saline	21	23.28	8.31	0.942
	Corticosteroids	22	24.09	9.91	
Three months after treatment	normal saline	21	28.14	5.41	0.323
	Corticosteroids	22	29.81	5.94	

Mann-whitney u test

There was no statistically significant difference in the frequency of touch sensitivity in the two groups of patients (P>0.05; Table 4).

TABLE 4: The frequency of touch sensitivity in patients of two groups

Sensitive \ Group		normal saline	Corticosteroid	Total	P-value
Before intervention	Number	19	20	39	0.961
	Percent	90.5%	90.9%	90.7%	
One month after treatment	Number	5	6	11	0.795
	Percent	23.8%	27.3%	25.6%	
Three months after treatment	Number	7	8	15	0.835
	Percent	33.3%	36.4%	34.9%	

The mean and standard deviation of the satisfaction score in the patients of the two groups did not show a statistically significant difference (P>0.05) (Table 5).

TABLE 5: Average and standard deviation of the satisfaction score in the patients of the two study groups

group	Number	Mean	P-value
normal saline	21	3.14±0.96	0.683
Corticosteroids	22	3.27±0.98	

DISCUSSION

Lateral epicondylitis is usually associated with chronic disability and proper treatment with full effect has not been introduced, so finding a way to treat this disease is of particular importance (5). Therefore, the purpose of this study was to investigate the effect of corticosteroids on the pain and performance of patients with tennis elbow. In this study, a total of 21 patients in the normal saline group and 22 in the corticosteroid group were analyzed, of which 20 patients (46.5 %) were male and 23 (53.5%) were female. The average age of the subjects studied was 40.27 ± 9.11 years. This study showed that there was no statistically significant difference between the two groups in terms of pain and performance score and sensitivity to touch and satisfaction between the two groups.

Lebiedzinaki et al investigated the effect of Autoroyars Condrienol Pluoma injection (Acp) compared to corticosteroid injection (Betamethasone) during a one-year follow-up.

Patients were randomly assigned to one of two groups, both groups were comparable with the initial DASH score, 53 were treated with ACP, and 46 with 1 ml betamethasone injections and 2 ml of 1 % lignocaine.

After 6 weeks, the DASH score was significantly better in the betamethasone-treated group and improved but was better in the ACP -treated group after one year. Full recovery at all-time points was more common was found in the betamethasone group. DASH scores demonstrated good resultsfindings in the ACP group after one year. More patients showed pain symptoms of injection in the ACP group when compared with the betamethasone group (12). In the present study, it was also found that corticosteroid injection significantly reduced pain and DASH score in patients during one month, but this reduction was also seen in the normal saline group.

Murtezani et al. (2015) investigated the effectiveness of corticosteroid injection and physiotherapeutic interventions (ultrasound and exercise) in the treatment of chronic cases of these patients in a randomized controlled trial. The results showed the usefulness of ultrasound and exercise treatment for these patients (16). While the present study showed that corticosteroid injection significantly reduced pain and DASH score, and on the other hand, it caused a significant decrease in the frequency of sensitivity to touch in patients in the first month after injection, but pain and DASH score were increasing after 3 month, these findings were also seen in the normal saline group.

Ozturan et al in a study in Turkey have investigated the Corticosteroid injection, autologous blood injection, and extracorporeal shock wave therapy in the treatment of lateral epicondylitis., in which 60 people (32 women and 28 men) were randomly divided into three groups. The outcomes were evaluated at 4, 12, 26, 52 weeks, corticosteroid injection revealed significantly better results for all four weeks according to the mentioned criteria. Success rates in the 3 groups were determined to be 90%, 16.6%, and 42.1%, respectively. Autologous blood injection and extracorporeal shock wave was found to show significantly better Thomsen provocative test results and upper extremity functional scores at 52 weeks; the success rate of corticosteroid, autologous blood injection and shock wave therapy was found to be 5%, 83% and 89%, respectively (11).

In this study, it was also found that corticosteroid injection had a favorable effect on both pain and function. Corticosteroid significantly reduced pain and improved patients' performance in the first month after treatment, but a slight return in the scores of both variables occurred in the long term. These effects were also seen regarding the injection of normal saline. These findings regarding the lack of effect of corticosteroid injection on performance are opposite to the results obtained from the present study, which may be due to the sample size, follow-up period, and demographic indicators of patients, as well as inclusion and exclusion criteria, and sampling method.

In 2011, a study was conducted comparing autologous blood injection, corticosteroid and normal saline injection in the treatment of lateral epicondylitis in a period of less than 6 months in 28 people. The patients were followed up 6 months after the injection and their results showed a decrease in DASH, function and pain scores. They were given stretching exercises that measured them in an acceptable range. All 3 injections resulted in reductions in DASH scores at 2 weeks and 2 months follow-up points and significant reductions at 6 months; however, there was no significant difference between the two groups. In addition, patients reported improved pain and function scores among both groups (17).

While the current study showed that both corticosteroid injection and normal saline treatment improved the pain and function of the patients in terms of the DASH questionnaire in the short term, but similar to normal saline, symptoms returned in the long term (after 3 months), where the pain score increased between 0.5 and 1 unit and the DASH score increased between 5 and 10 units. Therefore, it can be seen that corticosteroid injection is not superior to normal saline and both methods are ineffective in terms of long-term effects, while they are more effective in the short term. Other methods are needed for long-term progressive improvement.

Krogh et al (2013) investigated effect of platelet-rich plasma (PRP), glucocorticoid or saline in reducing pain in adults with Lateral epicondylitis after 3 months, where steroid was more effective in reducing pain in 1 month compared to saline

or platelet-rich plasma injection, but neither injection of PRP nor glucocorticoid was found to be superior to saline regarding pain reduction at 3 months. In addition, corticosteroid injections have been shown to result in decreased collar Doppler activity and tendon thickness when compared with other conditions, placing patients at greater risk for adverse effects (18). Regarding the same therapeutic effects of normal saline and corticosteroid injection and the side effects of corticosteroid injection, in the meantime, the best treatment method is normal saline with limited side effects.

Corticosteroid injections also have several adverse effects, the most serious of which is tendon rupture. These adverse effects have been reported in many clinical studies that evaluated the effectiveness of corticosteroid injections. Adverse effects appear to be present for all injection methods except platelet-rich plasma and sclerosant (19). Therefore, it is necessary to investigate other methods such as platelet-rich plasma injection and Sclerosant or saline in future studies in order to reach the best treatment method in these patients.

CONCLUSION

Based on the data presented herein, both corticosteroid injection and normal saline treatment were capable of improving the pain and function of the patients in terms of the DASH questionnaire in the short term, but similar to normal saline, symptoms returned in the long term. Corticosteroid injection was not found to be superior to saline, when both methods were ineffective in terms of long-term effects, while they were more effective in the short term.

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