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The effects of corticosteroid injection versus local anesthetic injection in the treatment of lateral epicondylitis: a randomized single-blinded clinical trial

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Abstract
Introduction This study seeks to compare two treatment methods of lateral epicondylitis: corticosteroid injection (CSI) and a local anesthetic injection (LAI).
Materials and methods In this single-blinded randomized clinical trial, 138 patients with the diagnosis of lateral epicondylitis were assigned either into CSI group receiving methylprednisolone 1 ml (49 patients) or LAI group (51 patients) receiving procaine 1 ml 2 % in a single dose at the maximal point tenderness site. The primary outcome measure was elbow disability using Quick DASH, and secondary outcome measures were pain intensity using Visual Analogue Scale (VAS) and recurrence rate at pre-treatment visit and at 3-, 6- and 12-week post-treatment visits.
Results There were no significant differences between the patients in both groups for demographic factors including age, gender, dominant hand, involved hand, and work pressure. Before treatment, the patients in both groups were suffering from the same rates of elbow disability and pain as measured by Quick DASH and VAS, respectively, ($p > 0.05$). In general, the recovery rate (comparison between pretreatment visit and last post-treatment visit) was significantly more effective and higher in CSI than LAI. CSI was dramatically more effective at 3-week visit, but less and less effective at 6- and 12-week visits. At 12-week visit the recurrence rate was 34.7 % (17 patients) in CSI group.
Conclusion For lateral epicondylitis, CSI has the best short-term treatment results yet the highest recurrent rates. The combination of CSI with other treatment option or with a change in injection technique from single injection to peppering injection may be promising.

Keywords Tennis elbow · Lateral epicondylitis · Intra-lesional injection · Corticosteroids · Local anesthetic · Visual analogue scale · Treatment outcome

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Introduction

Lateral epicondylitis is a common disorder characterized by the lateral elbow pain and tenderness. Despite the general belief, relatively few proportions of patients (5 %) develop epicondylitis for playing with rackets such as tennis [1–3]. The incidence of epicondylitis is 1–4 % in general population and 15 % in high risk industrial workers [4, 5]. Epicondylitis generally occurs among adults over 40, with the pick incidence between 35 and 55 years of age, involving men and women equally. The patient's

history indicates repetitive activities during work and daily routines [5, 6].

Recent studies demonstrate that epicondylitis is more of a degenerative condition than an inflammatory one [3, 7–10]. The inferior aspect of the extensor common tendon, particularly extensor carpi radialis brevis (ECRB) is in contact with capitellum and slides along its lateral edge during elbow extension–flexion movements. This constant sliding and abrasion may be the main cause of developing epicondylitis [5, 11]. The repeated stretching and the subsequent micro tears lead to tissue degenerative process, immature repair and finally tendinosis. Lack of appropriate and adequate vasculature of the undersurface of the tendon contributes to constant and progressive degenerative tendinosis [3, 8, 10, 11].

A history of pain associated with the lateral aspect of the elbow during exertion is the main symptom of lateral epicondylitis. The symptoms tend to develop following resisted supination or wrist dorsiflexion particularly with the arm in full extension. Generally, the pain is distal to lateral epicondyle above the length of extensor tendon [5, 11]. Treatment options are wait-and-see strategy, education and behavioral treatment, bracing, laser therapy, physiotherapy, oral NSAIDs administration, corticosteroid injection (CSI), local anesthesia injection, autologous blood injection, botulinum toxin injection, acupuncture, ESWT, iontophoresis, prolotherapy and surgery; However, there is no consensus on the preferred treatment [5, 10, 12–19].Although the CSI has proved to have better outcomes among other palliative treatments [20, 21], certain studies reported the recurrence rate of the lateral epicondylitis in 50–66 % of the patients following 6 months of the treatment [22]. Variety of risk factors and side effects has been reported to accompany CSI in the treatment of lateral epicondylitis. A review study provides a list of most common complications as osteomyelitis, cellulitis, ecchymosis, and local dermatological effects such as atrophy of subcutaneous fat, hypopigmentation, and damage to the skin structure [23].

Despite the common prevalence and considerable burden of lateral epicondylitis in our population and variety of treatment options, the reliable well-designed (blinded and randomized) clinical trials to support one treatment over the other is limited. The present randomized blinded clinical trial was undertaken to examine and compare CSI (corticosteroid injection: methylprednisolone acetate) versus a LAI (local anesthetic injection: procaine).

Materials and methods

A randomized single-blinded clinical trial was conducted on patients with lateral epicondylitis, referred to our orthopedic clinical department during 2010–2011. The inclusion criteria were: adults over the age of 18 with symptomatic unilateral pain (VAS >6) at the lateral aspect of the elbow for more than 6 weeks, tenderness in the lateral epicondyle of the elbow at the tendon and common extensor muscle joint and pain during resisted extension of the wrist during full elbow extension. The exclusion criteria were: history of the instability of the elbow, previous trauma or fractures of the elbow, history of surgery or arthritis of the elbow, bilateral involvement of the elbow, accompanied pathology at cervical spine, confirmed carpal tunnel syndrome, history of CSI or LAI to the suffered elbow, systematic corticosteroid treatment, and any contraindications to LAI or CSI (such as hypersensitivity, systemic infection, poor controlled diabetes, history of increased sensitivity to local anesthesia, pregnant or lactating women). After taking the patient's history and physical examination, the following information were recorded in the questionnaires: demographic characteristics, baseline assessments including age, gender, the dominant hand, the involved hand, the onset of the condition, referral date, and patient's occupational status in three categories unemployed, employed (having a job for a living for a minimum of 1 year) with an occupation requiring repetitive hand work and occupation requiring minimal hand work. The study was conducted in accordance with ethical standards of Helsinki and the patients were briefed about the possible side effects of both treatment options and all the patients signed the informed consent forms prior to enrolment.

In accordance with previous studies and considering the Quick DASH scales (disabilities of the arm, shoulder and hand), the sample size was calculated to be 45 patients in each treatment group with a loss of 20 %, power of 90 %, and confidence interval of 95 %. The initial sample size in the present study was 138 patients, of whom 11 did not fulfill the inclusion criteria and 13 refused to sign the informed consent forms. Thus, after fulfilling the inclusion criteria and clinical confirmation, a total of 114 patients were randomly assigned to either CSI group ($n = 55$) or LAI group ($n = 59$) by means of a random block design (Fig. 1). Patients in CSI group received a single dose of methylprednisolone acetate 1 ml locally at the maximal point tenderness and those in LAI group received procaine 1 ml 2 % at the same site. All the injections were performed by the first author of the study. To ensure the blinding and concealment, the syringes were filled in the absence of the patients and the patients were asked to look at the opposite side during injections. All patients in both groups were asked to use braces, have adequate rest and have limited physical activities. The elbow disability scale, as the primary outcome measure, was defined using Quick DASH questionnaire containing 11 multiple choice questions (5 choices for each question), in that, each patient

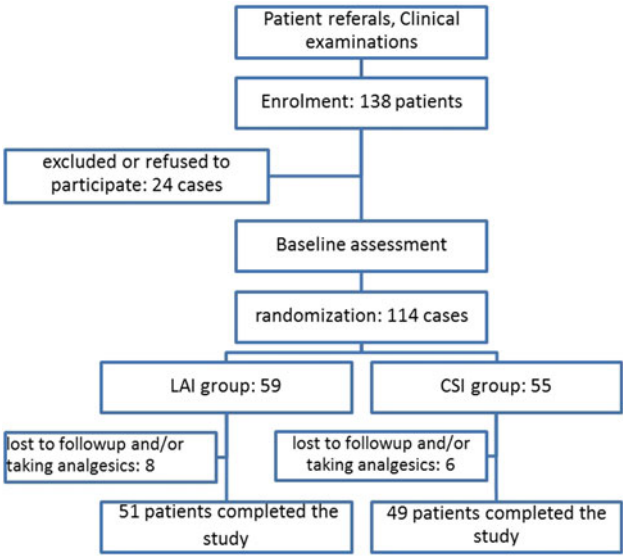

Fig. 1 Enrollment flow-chart

could receive a rating between 0 (best condition) to 100 (worst condition). The severity of pain, as the secondary outcome measure, was defined using VAS questionnaire, in that, 0 indicated experiencing no pain and 10 as the highest imaginable pain. The recurrence rate was defined as an increased VAS score to 50 % at 12-week post-treatment visit as compared with 3- or 6-week visits. The Quick DASH and VAS questionnaires were filled out at 3-, 6- and 12-weeks post-treatment.

Frequency tables and charts were used to summarize the data. The qualitative values were expressed as frequencies and relative frequencies (percentages) and the quantitative values as means and standard deviations. The differences between both groups were assessed by Chi-squared and independent sample *t* test. The repeated measure analysis of variance was used to compare the pretreatment and post-treatment assessments at 3-, 6-, and 12-month visits in both groups. The interactions among the interfering factors (such as age, gender, dominant hand, involved hand and occupation) and the quick DASH and VAS scales were analyzed for both groups using the repeated measure analysis of ANOVA. The statistical data analysis was performed using SPSS version 19 software (Chicago IL USA). A p value of <0.05 was considered to be significant.

Results

In general, 49 patients in CSI group and 51 in LAI group completed the study. There were no significant differences between the two groups according to demographic factors such as age, gender, dominant hand, involved hand, and occupation (Table 1). The VAS and quick DASH scores were similar between the two groups before treatment ($p > 0.05$).

The primary and secondary outcomes of the study were defined as the changes in the instability of the elbow presented as Quick DASH scores and VAS scores at three follow-up visits (Table 2). The repeated measure analysis of variance indicates significant changes in the Quick DASH and VAS scores in both groups ($p < 0.0001$). However, the trends of changes were not similar between the two groups, in that success rate was higher in CSI group (Fig. 2a, b).

At 3-week visit, the patients in CSI group dramatically responded to treatment ($p < 0.0001$). The mean reductions in pain and disability of the elbow (VAS and Quick DASH scores) were 6 and 40 in CSI group, and 2 and 13 in LAI group, respectively, suggesting a threefold more effective response in CSI group than LAI group at 3-week follow-up

Table 1 The comparison of the demographic factors (age, gender, dominant hand, involved hand and occupation) and initial assessments (Quick DASH and VAS) before treatment

	CSI	LAI	Total	Statistics and data analysis
Number	49	51	100	–
Mean age ± SD	44.9 ± 9.6	44.6±8.1	44.7 ± 8.8	NS[¥]
Gender (male/female)	19/30	22/29	41/50	NS
Occupation (forceful hand work/low hand work/unemployed)	17/24/8	19/26/6	36/50/14	NS[†]
Mean symptom duration (week)	19	16	17	NS[¥]
Dominant hand (right/left)	45/4	43/8	88/12	NS[†]
Involved hand (right/left)	37/12	35/16	72/28	NS[†]
VAS score pretreatment (mean ± SD)	7.78 ± 1.3	7.80 ± 1.4	7.79 ± 1.4	NS[¥]
Quick DASH score pretreatment (mean ± SD)	57.17 ± 22.8	61.72 ± 23.1	59.49 ± 23	NS[¥]

SD standard deviation

[†] Chi-square test

[¥] Independent sample *t* test

Table 2 The mean of the VAS and Quick DASH scores pre- and post-treatment in CSI and LAI groups

Variables	Group	Pre-treatment	3-week	6-week	12-week
Quick DASH	CSI	57.2 ± 22.8	17.6 ± 20.9	19.9 ± 19.2	30.1 ± 21.9
	LAI	61.7 ± 23.1	48.5 ± 27.2	40.7 ± 27.6	38.6 ± 28.6
	Total	59.5 ± 23	33.6 ± 28.8	30.5 ± 25.9	34.5 ± 25.7
VAS	CSI	7.7 ± 3.1	1.7 ± 2.1	1.9 ± 2.3	2.8 ± 2.1
	LAI	7.8 ± 1.4	5.9 ± 2.4	4.7 ± 2.8	4.5 ± 2.7
	Total	7.8 ± 1.4	3.8 ± 3.1	3.3 ± 2.9	3.6 ± 2.6

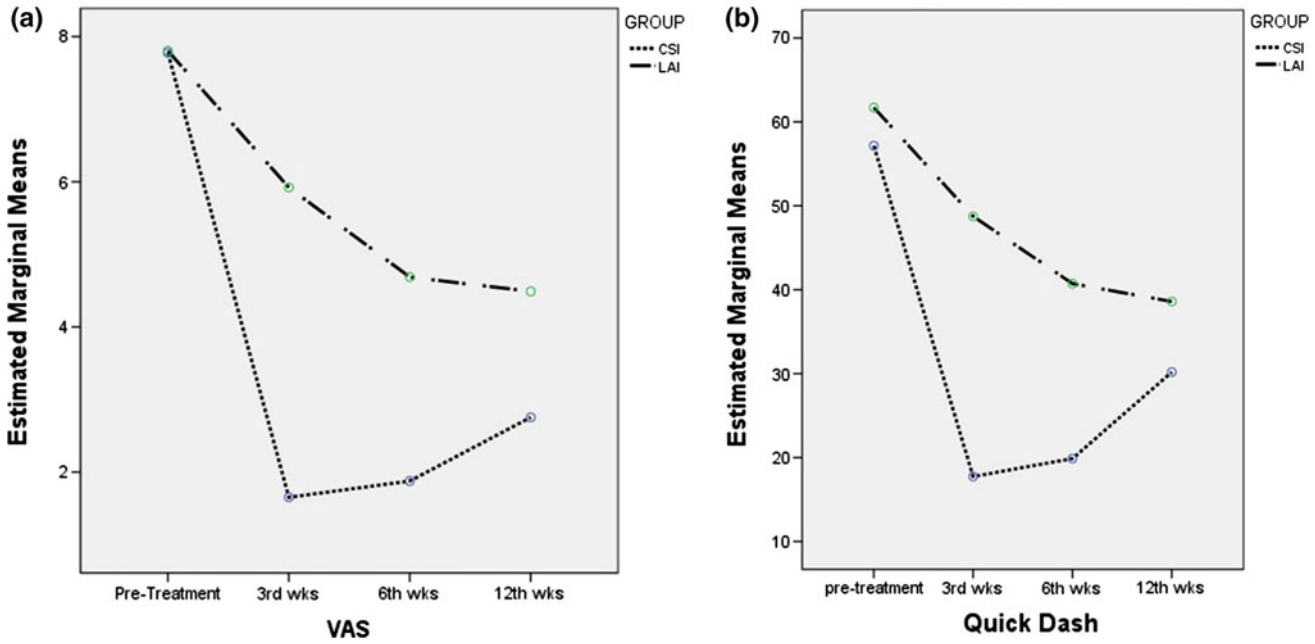

Fig. 2 **a**, **b** The mean changes of VAS and Quick DASH in CSI and LAI groups

visit. However, at 6- and 12-week follow-up visits, the response to treatment was reduced in CSI group (Fig. 2a, b). In CSI group, there were no significant changes in the mean of VAS and Quick DASH scores in 6-week follow-up visit rather than 3-week follow-up visit ($p > 0.05$). However, there was a significant increase in the mean of the VAS and Quick DASH scores at 12-week follow-up visit ($p < 0.05$). In this group, the VAS and quick DASH scores were 1.9 ± 2.3 and 19.9 ± 19.2 at 6-week follow-up visit and 2.8 ± 2.1 and 30.1 ± 21.9 at 12-week follow-up visit, respectively ($p < 0.05$), suggesting the recurrence of the disease in 17 out of 49 patients (34.7 %) in CSI group and none in LAI group. In LAI group, the mean VAS and Quick DASH scores were not changed significantly during follow-up visits.

The repeated measure analysis of variance showed no significant interactions among prognostic factors (age, gender, dominant hand, involved hand and occupation) and VAS and Quick DASH scores in both groups.

Discussion

A few systemic reviews have been conducted on the treatment of lateral epicondylitis with CSI technique [7, 9, 21, 24–28]. Labelle, in a review of 185 studies up to 1994, concluded that most of the studies suffer from methodological shortcomings and provide conflicting evidence for variety of treatment options [28]. Labelle argues that there is insufficient evidence to support one treatment option over another and the support for each treatment comes from anecdotal rather than scientific data. In a recent meta-analysis study, Krogh et al. [27] reviewed all types of injections in the treatment of lateral epicondylitis and

found out that 10 out of 17 studies (1,381 patients) used CSI technique. In the meta-analysis, the pooled results showed no significant difference between CSI and placebo in a long-term follow-up. They concluded that the unbiased randomized clinical trials investigating the effect of CSI in the treatment of lateral epicondylitis are too limited to decide conclusively in favor of a treatment option [27]. Bisset et al. in 2006 and smidt et al. in 2002 [10, 29], in two similar RCT studies evaluated the efficacy of CSI, physiotherapy and wait-and-see in the lateral epicondylitis and found out that CSI was more effective than the other two methods in short follow-up (<6 weeks). However, in a long-term follow-up, there was a significant increase in recurrent rate and significant reduction in therapeutic efficacy of CSI rather than the other two treatment options [10, 29].

In the short-term follow-up (2–6 weeks), CSI was reported to be superior to almost all of the other palliative techniques in terms of pain relief, overall improvement and grip strength [7, 9]. However, in average and long-term follow-up, NSAID and physiotherapy proved to be significantly better over the CSI treatment option [10, 30]. Randomized, prospective clinical trial studies need to be conducted to compare each treatment option with other treatments in separate studies to examine which treatment option has a better therapeutic outcome.

The literature for CSI does not provide conclusive evidence over the exact volume and type of corticosteroid injections, the exact area of injection (at the point of maximum tenderness or at anatomical position), and the injection method (single injection or injection using peppering technique) [7, 22, 31]. Price et al. evaluated the functional outcomes of following CSI regimens: triamcinolone 10 mg, hydrocortisone acetate 25 mg and lidocaine 1 % (as control group) and found out that CSI methods were more effective than LAI. However, Price did not find any significant differences between the two CSI methods. At 24-week follow-up, the improvement rate in all trial groups was similar and recurrence was observed in half of the patients undergoing CSI treatment [22]. Our study provides more evidence for Price's study indicating the superiority of CSI over LAI.

One possible reason for the ineffectiveness of CSI at long-term follow-up is that the tissue at injection position undergoes degenerative mucoid processes and disorientation of the collagen tissue rather than inflammatory processes [32]. The possible etiology of lateral epicondylitis are neurologic disorders secondary to the release of the chemicals (such as P substance and calcitonin gene-related peptides) from the primary sensory nerves [33, 34] and an increase of glutamate (an excitatory neurotransmitter and a well-known pain modulator in central nervous system) [32]. The glutamate neurotransmitters abundant in enthesopathies are responsible for pain transmission. Corticosteroids may be regarded as the main cause of dramatic relief of pain, due to its potential in fully inhibiting the neurotransmitters and their receptors. Thus, short-term relief of pain is just generated by analgesic effects of corticosteroids and the main pathology would remain intact. It is believed that high doses of CSI at degenerative site may inhibit the release of pro-healing cytokines, negatively impact tissue's reparative ability and ultimately postpone the disease self-limiting process [17].

Another purpose of the present study was to examine the effect of prognostic factors on CSI in the treatment of lateral epicondylitis. In the present study, the prognostic factors such as age, gender, the involved hand, dominant hand and occupation did not have significant effect on the treatment outcome. This is in agreement with the single similar study conducted on the effects of prognostic factors [35]. To examine the role of prognostic factors, Bisset et al. analyzed data from two randomized clinical trials (383 patients) comparing the results from the treatment of lateral epicondylitis using CSI, wait-and-see strategy, and physiotherapy. They found that CSI was more effective at 6-week post-treatment but significantly less effective at 1-year post-treatment. They revealed that patients' characteristics have insignificant prognostic effects [35]. Although the results of our study showed that occupational pressure does not have any effect on the treatment outcome, it needs to be more substantiated by further studies. We recommend subdividing the occupations and comparing the subgroups together. For instance, repetitive computer keyboard jobs, jobs involving non-neutral postures of hands and arms or use of heavy hand held tools need to be classified separately.

One limitation of the present study was the short follow-up time, in that we could not observe the outcome of the study in longer follow-up time. However, at this 12-week follow-up, we could observe the high recurrence rate (34.7 %) in CSI group and noticed that the CSI method is only effective in the first 3-week post-treatment and after that it is necessary to look for a substitute treatment option. The prospective design, randomization and concealing and blinding are considered as the strength points about the present study.

Conclusion

While CSI is the most common treatment option for lateral epicondylitis and has the best short-term outcome, it has the highest recurrence rate. The combination of CSI with other treatment options or with peppering technique may be promising.

Conflict of interest All named authors hereby declare that they have no conflicts of interest to disclose.

Ethical standards Guilan University of Medical Sciences Ethics Committee approved the study (reference number: 1910051505) and it was registered on the Iranian Registry of Clinical Trials (IRCT no.: IRCT201205127274N4).

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