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ORIGINAL ARTICLE

Comparison of the effects of sodium hyaluronate-chondroitin sulphate and corticosteroid in the treatment of lateral epicondylitis: a prospective randomized trial

Haci Bayram Tosun[1] · Seyitali Gumustas[1] · Ismail Agir[1] · Abuzer Uludag[1] · Sancar Serbest[2] · Demet Pepele[1] · Kadir Ertem[3]

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Abstract
Background Hyaluronic acid and glycosaminoglycans have shown positive effects in improving lateral epicondylitis and other tendinosis conditions. Therefore, we designed a prospective, randomized study to compare the effects of a combined sodium hyaluronate and chondroitin sulfate (HA + CS) injection versus a triamcinolone injection in the treatment of lateral epicondylitis.
Methods In total, 57 consecutive patients with clinically diagnosed lateral epicondylitis were divided randomly into two groups. In the HA + CS group, 25 patients received a single injection of a solution containing an HA + CS combination and prilocaine HCl, while the 32 patients in the triamcinolone group received a single injection of a solution of triamcinolone and prilocaine HCl. We evaluated the pain and function outcome measures using the Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire at the beginning of the study, and 3 and 6 months after the injection. Additionally, the Minimum Clinically Important Difference values and percentage changes in the PRTEE subscale scores between the assessments were calculated.
Results No serious adverse events were reported throughout the study. The mean pain and function scores for the HA + CS and triamcinolone groups had significantly improved at 3 months, but the mean function scores in the HA + CS group were statistically significantly better when compared to the triamcinolone group. At 6 months, both groups had significantly improved mean pain and function scores, compared to the baseline scores; however, the mean pain and function scores in the 6-month HA + CS treatment group were better than in the 6-month triamcinolone group. The relative change for the mean total score in the HA + CS group was much better when compared with the triamcinolone group, and the HA + CS treatment group showed clinically significant improvement when compared with triamcinolone group at 3 and 6 months.
Conclusions This study supports the idea that for a single injection treatment of patients with lateral epicondylitis, a combination injection of HA + CS may offer better pain benefits for 6 months after injection, when compared to triamcinolone.
Type of study/level of evidence Level II, Randomized Clinical Trial, Prospective Comparative Study.

Introduction

Many pharmacological and non-pharmacological treatment strategies have been proposed for the non-operative treatment of chronic tennis elbow in the medical literature. However, there is no strong evidence for the long-term benefit, and there is no consensus as to the best non-operative treatment for lateral epicondylitis [1, 2]. Surgical treatment is considered when functional disability and pain persist over the long term [3].

When used individually, hyaluronic acid (HA), and glycosaminoglycans (GAGs) have shown positive effects in improving lateral epicondylitis and other tendinosis conditions [1, 2, 4–8]. Given this background, we hypothesized that a combined composite solution of sodium hyaluronate

✉ Haci Bayram Tosun
bayramtosun@hotmail.com

[1] Department of Orthopaedics and Traumatology, Faculty of Medicine, Adiyaman University, 02100 Adiyaman, Turkey

[2] Department of Orthopaedics and Traumatology, Faculty of Medicine, Kirikkale University, Kirikkale, Turkey

[3] Department of Orthopaedics and Traumatology, Faculty of Medicine, Inonu University, Malatya, Turkey

(a hyaluronic acid, abbreviated as HA) and chondroitin sulfate (a glycosaminoglycan, abbreviated as CS) might be effective in the treatment of lateral epicondylitis. Thus, the aim of this prospective, randomized, and double-blinded study was to compare the effectiveness of a single local HA + CS combination solution injection, versus a single local triamcinolone injection, for the treatment of lateral epicondylitis.

Materials and methods

We performed a prospective, randomized study in an outpatient setting between March of 2013 and February of 2014 at our clinic. In total, 57 consecutive patients with clinically diagnosed lateral epicondylitis involving one elbow, who met the inclusion criteria, were included (Table 1). Approval was obtained from the medical research ethics committee (2013/16). All patients provided written informed consent and were allowed to withdraw from the trial for any reason at any time.

The patients were divided randomly into two groups and followed prospectively. The study was double-blinded, with the subjects, patients who were administered the injections, and the data management personnel all blinded to the contents of the injections. The physicians who administered the injections were different from those who evaluated the data.

Inclusion criteria for this study were: a history of at least 3 months of significant pain at the lateral epicondyle during daily activities, aged from 18 to 60 years, local tenderness to palpation just distal and anterior to the lateral epicondyle, and a positive response to at least one of three provocative tests (Table 2) [1, 9–11].

Exclusion criteria were: pregnancy or breastfeeding, a history of elbow surgery, neuromusculoskeletal or coagulation disorders, systemic or autoimmune disease, physical examination findings of nerve entrapment, allergy to local anesthetics or GAGs, and a history of injection treatment (corticosteroid or otherwise) or physical therapy within the previous 3 months. The previous use of oral medications for the treatment of lateral epicondylitis was not an exclusion criterion.

Table 1 Characteristics of treatment groups

	Triamcinolone	HA + CS	*p* value
Age, years (mean ± SD)	45.21 ± 8.6	46.84 ± 9.6	0.508
Sex (male), *n* (%)	20 (62.5)	13 (52)	0.42
Job (heavy work-related), *n* (%)	7 (21.9)	6 (24)	0.85
Dominant extremity (right), *n* (%)	28 (87.5)	23 (92)	0.68
Affected extremity (right), *n* (%)	26 (81.3)	19 (76)	0.62
Number of previous non-surgical treatment (mean ± SD)	2.18 ± 1.8	3.4 ± 3.9	0.12
Number of previous injections (mean ± SD)	0.65 ± 1.1	1.12 ± 2.1	0.29
Duration before presentation (months)	8.28 ± 9.7	14.12 ± 21.9	0.064
BMI (kg/m^2) (mean ± SD)	25.71 ± 5.5	26.29 ± 3.9	0.65
Lateral epicondyle tenderness, *n* (%)	32 (100)	25 (100)	–
Mill's test, *n* (%)	24 (75)	19 (76)	0.93
Cozen's test, *n* (%)	23 (71.9)	19 (76)	0.72
Maudsley's test, *n* (%)	26 (81.3)	22 (88)	0.71
Pain subscale score/50 point, mean (range)	32.2 (18–41)	30.3 (13–44)	0.28
Function subscale score/50 point, mean (range)	33.5 (13–47.5)	31.1 (10–46.5)	0.38
Total score/100 point, mean (range)	65.7 (35–86.5)	61.4 (28–90.5)	0.28

Table 2 Provocative tests

Cozen's test[a]	Stabilize the patient's forearm and instruct the patient to make a fist, pronate the forearm, and extend the wrist towards radial deviation, while the examiner resists this motion
Mill's test[a]	The examiner palpates the lateral epicondyle with one hand, and with the other, pronates the patient's forearm, flexes the wrist fully, and extends the elbow
Maudsley's test[a]	Resisted extension of the middle finger when the elbow is fully extended and the forearm is pronated

[a] Pain at the lateral epicondyle indicates a positive test

The 25 patients in the HA + CS group received a single injection of a 1.6 mL total dose mixture, comprised of 1 mL of an HA + CS combination (800 mg hyaluronate combined with 1 g chondroitin sulfate/50 mL) (Ialuril, IBSA Farmaceutici Italia S.r.l, Italy) and 0.6 mL of prilocaine HCl (Citanest, AstraZeneca PLC, London, UK). The 32 patients in the triamcinolone group received a single injection of a 1.6 mL total dose mixture comprised of 1 mL of triamcinolone acetonide (40 mg/mL) (Kenacort-A Retard, Bristol Meyers Squibb Pharmaceuticals, New York, NY, USA) and 0.6 mL of prilocaine HCl (Citanest).

After sterile preparation of the lateral epicondyle, the injections were administered as infiltrations over an area of 2 cm^2 under the external origin, immediately anterior and distal to the lateral epicondyle, which is the point of maximum tenderness [1, 2, 11]. The subjects were monitored for 30 min for any allergic reaction after the injection, and were then informed that they might experience a post-injection flare-up in the pain level. With the exception of acetaminophen (maximum dose of 1500 mg/day) and cold application, no other treatment (therapy, splinting, another injection, or anti-inflammatory medication) was rendered for the 6 months of the study. All patients were asked to avoid any activities causing pain in the elbow during the initial 3 weeks. Then, all of the subjects were reexamined within 48 h after each injection to ensure that no serious adverse effects had occurred. All patients were called 3 and 6 months after the injection.

Outcome evaluation

The patients were evaluated using the Patient-Rated Tennis Elbow Evaluation (PRTEE) questionnaire, which is a reliable, reproducible, and sensitive instrument for the assessment of chronic lateral elbow tendinopathy [10]. The PRTEE is a 15-item questionnaire designed to measure forearm pain and disability in patients with lateral epicondylitis. It allows the patients to rate their levels of tennis elbow pain and disability from 0 to 10 and consists of two subscales, pain and function [10–12]. Additionally, it has a function subscale including specific and usual activities [12]. The total score is the combined score that rates pain and disability as equal importance. A higher score indicates more pain and functional disability (e.g., 0 = no disability). The minimal obtainable score is 0 (best result), while the maximal obtainable "overall" score is 100 points (worst result) [10, 12]. Using a blinded reviewer, we collected the PRTEE questionnaire pain and function scores at the beginning of the study (baseline), at 3 months, and at 6 months after the injection.

Additionally, the Minimum Clinically Important Difference (MCID) values and percentage changes in the PRTEE subscale scores between the assessments were calculated. The MCID is the minimum amount of change that is needed to be meaningful to the patient, and when used as an outcome measure in trials of therapies, an MCID value is required to interpret the trial outcomes. The more stringent criterion of "much better" requires a 35–40 % improvement in the baseline scores to be confident that a meaningful level of improvement has occurred. Where a study reports a statistically significant difference between two treatments, but the actual change in the more effective treatment group's mean PRTEE score is <35 %, the value of the treatment remains open to question [13].

Statistical analysis

A sample size of 27 patients per group was necessary to detect a significant reduction in the pain and function scores with a two-sided 5 % significance level and a power of 80 %, in agreement with the study by Akermark et al. [1]. The SPSS software (ver. 12.0; SPSS Inc., Chicago, IL, USA) was used to analyze the data, and all data were compared using a 95 % confidence interval. The parametric data are presented as the mean ± SD. Intra-group comparisons were performed using paired *t*-tests and inter-group comparisons via independent sample *t*-tests. The non-parametric data were compared using the χ^2 test. To investigate the potential effects of the baseline severity on the MCID, separate analyses were conducted on the subgroups, defined by baseline total PRTEE scores of <40 and ≥40. This cut-off was selected post hoc to ensure reasonably sized subgroups for this sample.

Results

No subject withdrew from the study during the treatment phase, and all of the patients completed the study assessment period. No serious adverse events were reported throughout the study. The range of motion of the elbow joints of all patients was full at the baseline, and 3 and 6 month evaluations. Three patients in the HA + CS group developed moderate pain after the injection and were treated with acetaminophen and the local application of ice. There was transient pain after the injection in the triamcinolone group, but no drugs were administered.

The patient characteristics, medical histories, and physical examination findings are presented in Table 1; however, there was no significant difference between the triamcinolone and HA + CS groups at the baseline evaluation. Table 3 presents the mean pain and function scores of the groups, and Table 4 presents the results of the intra-group comparisons.

In the triamcinolone group, the mean pain and function scores improved significantly at 3 months versus the baseline scores. The mean pain score increased slightly after

3 months of treatment, and at 6 months, both the mean pain and function scores were significantly better than at the baseline. However, there was no statistically significant difference in the mean pain or function scores between 3 and 6 months.

In the HA + CS group, the mean pain and function scores improved significantly at 3 months versus the baseline scores. The improvement of the pain and function scores in the HA + CS group continued until the sixth month, then it decreased significantly at 6 months, versus the baseline scores. In contrast to the triamcinolone group, the pain scores in the HA + CS group continued to demonstrate statistically significant improvement in the mean pain scores between the 3-month and 6-month assessments ($p < 0.05$).

The mean pain scores for the HA + CS and triamcinolone groups did not differ significantly when comparing one group to the other at the baseline assessment or at the 3-month evaluation, but the mean function score in the HA + CS group was statistically significantly better than that of the triamcinolone group at the 3-month evaluation ($p < 0.05$). At 6 months, both groups maintained statistically better pain and function scores than at their baseline assessments, but the mean pain and function scores in the HA + CS group were statistically better than in the triamcinolone group ($p < 0.001$ for pain, $p < 0.05$ for function). Functional improvements in everyday jobs, work, recreational and sporting activities were particularly significant for the HA + CS group, compared to the corticosteroid group, at the 3- and 6-month follow-ups.

The MCID values and percentage changes for the subgroups with different PRTEE subscale scores at the baseline are presented in Table 5. The mean pain and function scores for the HA + CS had improved ≥40 % at 3 and 6 months, according to the baseline scores, but only the mean function scores for the triamcinolone group had improved ≥40 % at the third month.

The mean pain scores in the triamcinolone and HA + CS groups at 6 months versus the baseline decreased from 32.2 to 22.5 and from 30.3 to 11.7, and the mean function scores decreased from 33.5 to 20.4 and from 31.1 to 10.4, respectively. The percentage change in the subscale scores in the HA + CS group was much better than in the triamcinolone group at 3 and 6 months, versus the baseline. The number of "clinically much better" results in the HA + CS group was 19 (76 %), compared with 19 (59.3 %) of the triamcinolone treated patients, at 3 months, and 21 (84 %) compared with 15 (46.8 %) of the triamcinolone treated patients at 6 months.

Table 3 Mean pain and function scores in the triamcinolone and HA + CS groups and the results of inter-group comparisons

	Triamcinolone (mean ± SD)	HA + CS (mean ± SD)	*p* value
Pain score			
Baseline	32.25 ± 5.7	30.32 ± 7.8	0.28
3rd month	19.81 ± 10.8	15.12 ± 6.7	0.109
6th month	22.56 ± 12.9	11.72 ± 6.6	0.000*
Function score			
Baseline	33.50 ± 9.5	31.14 ± 10.5	0.38
3rd month	19.81 ± 12.4	12.28 ± 6.0	0.026**
6th month	20.40 ± 13.5	10.42 ± 6.6	0.005**

* $p < 0.001$

** $p < 0.05$

Table 4 Results (*p* values) of intra-group comparisons for pain and function scores

	Baseline vs. 3rd month	Baseline vs. 6th month	3rd month vs. 6th month
Pain score			
Triamcinolone	0.000*	0.000*	0.056
HA + CS	0.000*	0.000*	0.002**
Function score			
Triamcinolone	0.000*	0.000*	0.632
HA + CS	0.000*	0.000*	0.058

* $p < 0.05$

Table 5 MCID values for subgroups with different PRTEE scores at baseline

	Cut-off value							
	Baseline vs. 3rd month				Baseline vs. 6th month			
	Change score ≥40/100 (*n*)		Percentage change in total score (%)		Change score ≥40/100 (*n*)		Percentage change in total score (%)	
	Triamcinolone	HA + CS	Triamcinolone	HA + CS	Triamcinolone	HA + CS	Triamcinolone	HA + CS
Pain	19/32	17/25	38.59	46.02[a]	13/32	21/25	29.58	58.71[a]
Function	20/32	20/25	41.9[a]	56.67[a]	15/32	22/25	36.19	64.72[a]
Total	19/32	19/25	40.25[a]	51.35[a]	15/32	21/25	32.89	61.72[a]

[a] Clinically important different

Discussion

Corticosteroid injections are a commonly prescribed intervention for the management of lateral epicondylitis [14, 15]. Although corticosteroid injections are effective in reducing pain in the short term, they are also associated with risks of adverse events, high recurrence rates, and delayed recovery [15, 16]. Coombes et al. [4] reported that there was strong evidence for the benefits of corticosteroid injections in the short term (12 weeks), compared with non-injection interventions (NSAIDs, physical therapy, and orthotic devices) for the treatment of lateral epicondylitis. However, corticosteroid injections are less beneficial than other interventions in the intermediate term (26 weeks).

Despite a wealth of research, there is no consensus on the most efficacious management of tennis elbow, especially for effective long-term (≥52 weeks) outcomes [14]. Recently, there have been studies using glycosaminoglycan polysulfate (GAGPS) and HA injections for the treatment of lateral epicondylitis and supraspinatus tendinopathy [2, 5–8]. Glycosaminoglycans, such as HA and glucosamine N-chondroitin sulfate (glcN-CS) contribute to wound healing processes by creating an appropriate environment for growth, leading to the accumulation of other matrix proteins, the formation of growth and differentiation factors, and cell migration [17, 18]. HA stimulates mitosis and migration in epithelial cells and fibroblasts during the proliferative stage of wound healing [19]. Additionally, HA and glcN-CS contribute to the transformation of young tenoblasts into mature tenoblasts and tenocytes [20].

Hyaluronic acid has been used in certain soft-tissue disorders, including lateral epicondylitis [2], acute ankle sprain [21], supraspinatus tendinitis [5, 7], rotator cuff tears [8], Achilles tendinopathy, and plantar fasciitis [22], and its beneficial effects have been demonstrated. Petrella et al. [2] used periarticular HA injections in the treatment of lateral epicondylitis and found significant relief over the long term, as well as a more rapid return to sports activities in the HA group. The time to return to pain-free and disability-free sports was 18 (±11) days in the HA group (in 147 patients; 89 % response rate), but was not achieved in any of the control group (saline) patients. Meloni et al. [7] reported that periarticular HA injections showed higher efficacy in terms of the improvement of clinical symptoms and the recovery of a functional status in the patients with supraspinatus tendinosis than in the control group (saline). They suggested that this positive effect depended not only on decreased inflammatory processes, but also on a lubricating mechanical effect that loosened adhesion on the sliding surface of the tendon [7]. Petrella et al. [21] showed that periarticular HA injections in the treatment of acute ankle sprains are more effective than standard treatments (rest, ice, elevation, and compression). Finally, Kumai et al. [22] reported that HA injections for the treatment of lateral epicondylitis, patellar tendinopathy, insertional Achilles tendinopathy, and plantar fasciitis were effective.

The pharmacological properties of GAGPS described previously, such as the inhibition of thrombin and fibrin formation [23] and inhibition of catabolic enzymes active in connective tissue degeneration [24], could be of benefit, especially in chronic epicondylalgia [1]. Akermark et al. [1] reported that GAGPS injection therapy had good pain-relieving effects in chronic lateral epicondylalgia, although it caused some transient local pain and hematomas at the injection sites. The number of treatment failures in the GAGPS group at the 6-week follow-up was only four (13 %) compared with 12 (40 %) of the placebo (saline) treated patients. At the half-year follow-up, five of those who received GAGPS had experienced recurrence, and the recurrence rate at the 6-month follow-up was considerably lower than in the controlled studies with corticosteroids. In recreational athletes with Achilles peritendinitis, Sundqvist et al. [6] reported that injections of GAGPS had good overall therapeutic effects when compared with indomethacin.

Local injections of HA alone and GAGPS alone have demonstrated benefits in the treatment of tendinosis and lateral epicondylitis [1, 2, 4–7, 22], but different opinions have been reported (8, 25). Shibata et al. [8] reported that HA is an effective conservative treatment for patients with rotator cuff tears that do not require surgical repair, in which therapeutic efficacy in the SH (sodium hyaluronate) group was equivalent to that in the steroid group. Penning et al. [25] reported that HA injections were not able to show a convincing benefit when compared with corticosteroid or placebo injections in the treatment of subacromial impingement.

The goal of treating patients with tennis elbow is to improve pain, not to "restore" the tendon. However, we believe that lateral epicondylitis is not only the structural failure and inflammatory process as a result of ECRB tendon tears, but also insufficient tendon repair, which presents with angiofibroblastic degeneration. It is known that the goals of the operative treatment of tendinosis of the elbow are to resect the pathological material, stimulate neovascularization by producing focused local bleeding, and create a healthy scar while doing the least possible structural damage to the surrounding tissues; therefore, good results have been reported with surgical treatment in the literature [1, 3, 26, 27]. As a result, we hypothesized about what we could do in order to improve both the blood supply and structural damage, as well as to eliminate pain in the treatment of lateral epicondylitis. Oryan et al. [20] reported that the combination treatment of HA and glcN-CS in tendon repair has been demonstrated to decrease lymphocyte and macrophage infiltration, increase vasculogenesis, increase the number and maturity of the tenocytes, and reduce adhesion

formation. It also improves the differentiation, maturation, density, and alignment of collagen and the elastic fibrils. Ultimately, it contributes positively to the restoration of the tendon. Therefore, we suggest that the combined treatment might help in the resolution of both the symptoms and restoration, and there is no reported study on the use of a single local HA + CS combination solution injection in the treatment of lateral epicondylitis. However, it must be emphasized that a comparison should be made between the control group and each of the drugs alone, and we do not know whether the combined treatment may have a synergistic or additive effect.

We compared the effectiveness of a single local HA + CS combination solution injection versus a single local triamcinolone injection for the treatment of lateral epicondylitis. The corticosteroid was used because corticosteroid injections are the most performed method in the treatment of lateral epicondylitis and they are the most commonly used technique for clinical studies in the literature [4, 14–16]. Furthermore, there was no serious adverse event in either group. One of the most important limitations of this study is the lack of comparison between the control group and each of the drugs alone, so further studies should be conducted.

The baseline scores of the groups did not differ significantly, and after treatment, the mean pain and function scores for the HA + CS and triamcinolone groups were statistically significantly improved at 3 months versus the baseline scores. However, the reduction of the mean function scores in the HA + CS group was statistically significant when compared to the triamcinolone group. At 6 months, both groups had significantly improved mean pain and function scores, but the mean pain and function scores in the HA + CS group were better than the triamcinolone group.

The mean pain and function scores for the HA + CS group showed clinically significant changes according to the baseline scores at 3 and 6 months, but in the triamcinolone group, only the mean function scores had a clinically significant change at 3 months. The MCID values and relative change for the mean total scores in the HA + CS group were much better than in the triamcinolone group.

In conclusion, the HA + CS injection was more effective than triamcinolone in terms of clinically significant improvement and the functional outcomes at 3 and 6 months, and it was more effective in terms of pain relief at 6 months. Our study has some limitations, including the small sample size, lack of a control group, short follow-up, use only PRTEE questionnaire to evaluate the outcomes, and lack of a cost-effectiveness analysis, so further studies are needed. Despite this, we obtained encouraging results, reinforcing our belief that an HA + CS injection is a valid tool in the conservative treatment of lateral epicondylitis which does not respond to other non-operative treatments. This study supports the hypothesis that for a single injection treatment in patients with lateral epicondylitis, a combination injection of HA + CS may offer better pain benefits for 6 months after injection, when compared to triamcinolone.

Conflict of interest This author, their immediate family, and any research foundation with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject of this article.

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