



Prospective Study of the Autologous Blood, Corticosteroid Injection in the Treatment of Lateral Epicondylitis in Term of Clinical and Functional Outcome

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Abstract

Background: The purpose of this study was to compare the effectiveness of autologous blood and corticosteroid injections for lateral epicondylitis in a randomized trial.

Methods: Hospital based prospective comparative randomized intervention study conducted at Department of Orthopaedics, SMS Hospital & Attached Hospital to SMS Medical College, Jaipur.

Results: The VAS score and nirschl staging was found to be improved in steroid group at end of 2nd week after

injection, but the final outcome at 12th week was found to be better for blood group.

Conclusion: To conclude injection technique using steroid or autologous blood is easy and of value for the patients. Among these two, steroid injection once considered as a gold standard therapy for tennis elbow produces symptomatic relief in short times, but recurrence of the disease is problematic. Autologous blood injection produces a slow but long lasting effect and also prevents recurrence.

Keywords: Autologous blood, Steroids, VAS score.

Introduction

Tennis elbow (also known as "shooter's elbow" and "archer's elbow") is a condition where the outer part of the elbow becomes sore and tender. It is commonly associated with playing tennis and other racquet sports. However, any activity that involves repetitive twisting of the wrist (like using a screwdriver) can lead to this condition. Therefore, painters, plumbers, construction workers, cooks, and butchers are all more likely to develop tennis elbow. This condition may also be due to constant computer keyboard and mouse use.

Tennis elbow is a "frequent cause of elbow pain and wrist dysfunction. The disorder develops insidiously and is usually related to repetitive and strenuous physical activity and stress, mostly applied to the the origin of the extensor carpi radialis brevis.¹ Sports persons as well as those who used the same repetitive motions for many years, especially in their profession, suffer from tennis elbow. It is also common in individuals who perform motions they are unaccustomed to. The data also mentioned that the majority of patients suffered tennis elbow in their right arms. Tennis elbow affects men and women equally, with a prevalence of 1% - 3% in the general population².

The purpose of this study was to compare the effectiveness of autologous blood and corticosteroid injections for lateral epicondylitis in a randomized trial.

Our null hypothesis was that autologous blood injection would perform comparably to corticosteroid injections, as measured by standardized outcomes measures. Patient were follow up at 1st week, 4th and 12 week. Pain and disability assessed with visual analogue scale (VAS) and Nirshal staging.

Materials And Methods

Study Area: Department of Orthopaedics, SMS Hospital & Attached Hospital to SMS Medical College, Jaipur.

Study Duration: Data collection for the study was started just after the approval from institutional research review board and ethical committee, upto June 2019 or September 2019.

Study Design: Hospital based prospective comparative randomized intervention study.

Sample Size: Sample size was calculated at study power 80% and alpha error of 0.05 assuming standard deviation 0.8 in VAS score in steroid group at 12 week as found in seed article.

For minimum detectable mean difference of 0.6 in VAS score 28 patients in each of two group is required as sample size which is further enhanced and rounded off to 35 patients in each of 2 group as final sample size for present study expecting 20% dropout / loss to follow up / anticipate 12 week follow up.

Randomization method

Randomization will be done by simple random technique through chit box method.

Study Universe:

Patient who attend Department of Orthopaedics in SMS Medical College and Attached Groups of Hospitals, Jaipur with lateral Epicondylitis.

Inclusion Criteria

1. Patients between age group of 18 to 60 years presenting with complaints of pain, worse with exercise / routine activities, relieve on rest present for 2-3 weeks or more.
2. Patients with maximal tenderness at the attachment of the extensor carpi radialis brevis lateral epicondyle.

3. Willingness to participate in an investigational technique and follow-up with written consent.
4. Willingness to forgo any other concomitant conservative treatment modality; NSAIDS and orthotic devices during the study period.

Exclusion Criteria

1. Previous surgery for elbow pain.
2. Hb value less than 11 gm/dl and thrombocyte count less than 150000/mm³.
3. Previous treatment: Corticosteroid injection in the last 6 month or NSAIDS treatment within last 7 days.
4. A history of substantial traumas.
5. Extensor carpi radialis brevis tendon pathology.
6. Pregnant or breastfeeding female patients.
7. Other causes of elbow pain such as osteochondritis dessecas of capitellum, lateral compartment arthrosis, varus instability, radial head arthritis, posterior intosseous nerve syndrome, cervical disc syndrome, synovitis of radiohumeral joint, cervical rediculopathy, fibromyalgia, osteoarthritis of elbow, carpel tunnel syndrome.

Method

After taking clearance from ethical committee, patients was selected according to inclusion and exclusion criteria. Informed written consent was taken from every patient who agreed to follow instructions and recommendation given by the clinician. Patient biography, detailed history, clinical examination and investigation was done.

Patients was randomly allocated in two groups

Group A- 2 ml of venous blood, drawn from the contralateral upper limb and was injected locally after mixing with 1 ml of 2% lignocaine solution.

Group B: These patients was treated with single injection of Depo-Medrol (methylprednisolone acetate) 40 mg/ml,2 cc locally.

Statistical Analysis

The data will be compiled in MS Excel in the form of master chart. The data will be analysed as per aim & objectives. Inference will be drawn with the use of appropriate significant tests (chi square test for qualitative data & unpaired t test for quantitative data). For significance p value 0.05 will be considered as cut off point.

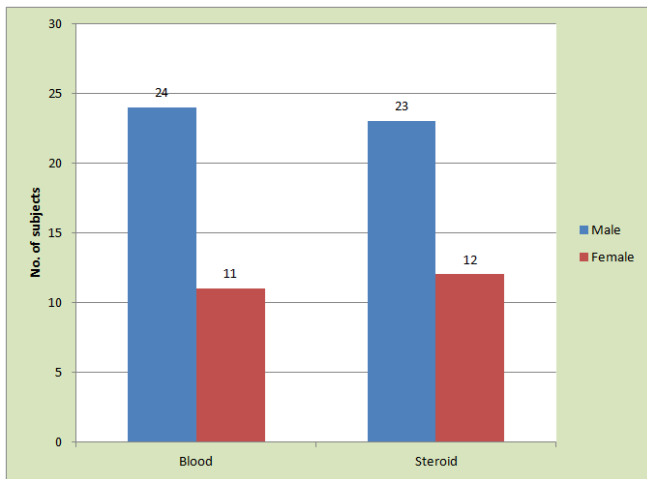
Results

Table 1 : Age distribution of study groups

Age group (years)	Blood		Steroid		Total	
	N	%	N	%	N	%
<30	1	2.9	3	8.6	4	5.7
30 – 39	12	34.3	14	40.0	26	37.1
40 – 49	13	37.1	12	34.3	25	35.7
50 – 60	9	25.7	6	17.1	15	21.5
Total	35	100	35	100	70	100
Mean± SD	44.11 ± 08.29		40.51 ± 09.15		42.31 ± 08.86	

t test: t=1.72, at 68 degree of freedom; p value 0.089(NS)

The above table shows the age distribution of the patients of steroid & blood group. Out of 35 patients of blood group 25 (34%) were lying in the age group of 30-49 years where as out of 35 patients of steroid group, 26 (35.7%) were lying in the same age group. The mean age of steroid & blood group patients 40.51 ± 09.15 & 44.11 ± 08.29 respectively. The difference in two group with respect to age was not significant p value 0.089 (NS).



Out of 35 patients of blood group 24 (68.6%) male patients were lying in the steroid group 23 (65.7%) out of 35 patients remaining are female patients.

Table 2: VAS Score at different follow up in autologous blood group

	VAS Score (Mean ± SD)	P value(ANOVA)
Baseline	6.02 ± 0.95	<0.001(S)
At 1 week	4.94 ± 0.90	
At 4 week	3.82 ± 0.92	
At 12 week	0.71 ± 0.75	

The above table shows Mean ± Sd of VAS at different interval of blood group the mean ± sd of VAS score at pre level in blood group patient was 6.02 ± 0.95. Similarly at 1 week the mean ± sd of VAS score in blood group patients 4.94 ± 0.90 and 4 weeks week the mean ± sd of VAS score in blood group patients 3.82 ± 0.92 and at the end of 12 weeks week the mean ± sd of VAS score in blood group patients 0.71 ± 0.75.

It was observed the mean VAS of blood group patient was found to be lesser as compare to steroid group patient at different level.

Table 3: VAS Score at different follow up time in Steroid group

	VAS Score (Mean ± SD)	P value(ANOVA)
Baseline	5.77 ± 1.05	<0.001 (S)
At 1 week	4.80 ± 1.07	
At 4 week	3.48 ± 1.12	
At 12 week	0.94 ± 0.76	

The above table shows Mean ± Sd of VAS at different interval of steroid group the mean ± sd of VAS score at pre level in steroid group patient was 5.77 ± 1.05. Similarly at 1 week the mean ± sd of VAS score in blood group patients 4.80 ± 1.07 and 4 weeks week the mean ± sd of VAS score in blood group patients 3.48 ± 1.12 and at the end of 12 weeks week the mean ± sd of VAS score in blood group patients 0.94 ± 0.76.

Table 4: Comparison of mean VAS Score among the groups

	Blood Mean ± SD	Steroid Mean ± SD	P value (t test)
Baseline	6.02 ± 0.95	5.77 ± 1.05	0.302 (NS)
At 1 week	4.94 ± 0.90	4.80 ± 1.07	0.554 (NS)
At 4 week	3.82 ± 0.92	3.48 ± 1.12	0.163 (NS)
At 12 week	0.61 ± 0.52	0.93 ± 0.61	0.002 (S)

The above table shows Mean ± Sd of VAS at different interval of blood group the mean ± sd of VAS score at pre level in blood group patient was 6.02 ± 0.95. Similarly at 1 week the mean ± sd of VAS score in blood group patients 4.94 ± 0.90 and 4 weeks week the mean ± sd of VAS score in blood group patients 3.82 ±

0.92 and at the end of 12 weeks week the mean \pm sd of VAS score in blood group patients 0.61 ± 0.52 .

The above table shows Mean \pm Sd of VAS at different interval of steroid group the mean \pm sd of VAS score at pre level in steroid group patient was 5.77 ± 1.05 . Similarly at 1 week the mean \pm sd of VAS score in blood group patients 4.80 ± 1.07 and 4 weeks week the mean \pm sd of VAS score in blood group patients 3.48 ± 1.12 and at the end of 12 weeks week the mean \pm sd of VAS score in blood group patients 0.93 ± 0.61 .

Similarly the mean change in VAS at 12 weeks in steroid group & blood group was 0.93 ± 0.61 & 0.61 ± 0.52 respectively. The difference in fall of VAS was found to be significant.

Table 5: Distribution of VAS at various intervals among autologus blood group

VAS Score	Follow up time			
	Baseline	At 1 week	At 4 week	At 12 week
0	0	0	0	16
1-3	0	2	11	19
4-6	23	32	24	0
7+	12	1	0	0
Total	35	35	35	35

Chi Square = 137.2, df 9, p value <0.001 (S)

In blood group of 35 patients with +7 VAS score before injection were 12 and at end 4th week and 12th week were nil, patients with 4-6 VAS score before injection were 23 but at end of 4th and 12th week after injection was 24 and nil respectively. Patient with 1-3 VAS score before injection were nil and number of patient with 0 VAS score were nil at pre injection and at end of 4th week and nil and were 16 at end of 12th week.

Table 6: Distribution of VAS at various intervals among steroid group

VAS Score	Follow up time			
	Baseline	At 1 week	At 4 week	At 12 week
0	0	0	0	10
1-3	1	4	17	25
4-6	26	30	18	0
7+	8	1	0	0
Total	35	35	35	35

Chi Square = 110.8, at degree of freedom 9, p value <0.001 (S)

In steroid group of 35 patients with +7 VAS score before injection were 8 and at end 4th week and 12th week were nil, patients with 4-6 VAS score before injection were 26 but at end of 4th and 12th week after injection was 28 and nil respectively. Patient with 1-3 VAS score before injection were 1 but at end of 4th and 12th week after injection were 17 and 25 respectively and number of patient with 0 VAS score were nil at pre injection and at end of 4th week and were 10 at end of 12th week.

Table 7 : Comparison of NIRSCHL Stage among study groups

	Blood	Steroid	P value (t test)
	Mean \pm SD	Mean \pm SD	
Baseline	5.40 ± 0.91	5.42 ± 1.11	0.933 (NS)
At 1 week	4.37 ± 0.94	4.22 ± 1.13	0.542 (NS)
At 4 week	3.14 ± 0.94	2.88 ± 1.13	0.291 (NS)
At 12 week	0.80 ± 0.86	1.71 ± 1.36	0.001 (S)

The above table shows Mean change \pm Sd of NIRSCHL stage from pre to different interval of Steroid and blood group patients, 4 week follow up and at 12 week follow up in both the groups. The mean NIRSCHL stage in the steroid group was 2.88 ± 1.13 , 3.14 ± 0.94 , 1.71 ± 1.36 and 0.80 ± 0.86 at the pre treatment, 4 weeks and 12 week follow up respectively.

Table 8: Comparison of response status between the groups

Response	Blood		Steroid		Total	
	N	%	N	%	N	%
Yes	32	91.4	30	85.7	62	88.6
No	3	8.6	5	14.3	8	11.4
Total	35	100	35	100	70	100

Chi Square = 0.565, at degree of freedom 1, p value = 0.710 (NS)

The above table depicts 32 patients treated with blood well response out of 35 and 30 patients treated with steroid well response out of 35 remaining not response.

Discussion

The age of patients selected for blood group and steroid group are in the range of 31-56 years and 26-50 years respectively. The maximum number of diseased were between 35-44 years of age and the mean age of these groups are 44.11 ± 8.29 (blood group) and $40-51 \pm 9.15$ (steroid group). There were 23 males out of 35 in blood group and remaining were females. Thus tennis elbow is prevalent in the 3rd decade population. In old literature, it was shown that the disease affects equally males and females, but in our study there is slight predominance of the problem in male counterpart, this may be attributed to the negligence of the problem by female counterpart or due to smaller group.

In blood group of 35, 27 patients have tennis elbow in right side and in steroid group of 35, 26 patients have on right side. Thus it shows that the problem tennis

elbow occurs mostly on predominant hand. In blood group 29 out of 35 patients had history of pain for <4 weeks and 6 out of 35 patients had history of pain for >4 week.

The VAS score and nirschl staging was found to be improved in steroid group at end of 2nd week after injection, but the final outcome at 12th week was found to be better for blood group. Thus injection of steroid produces a slow and long lasting benefit.

This study was designed to test the use of autologous blood injection Vs steroid injection in patients with lateral epicondylitis. The corticosteroid group was actually better initially and then declined, whereas the blood group progressively improved. There was a significant difference in decrease of pain and disability (NIRSCHL stage) of function following the blood application after 12 weeks. Lateral epicondylitis is a common problem with many available treatment methods. The most commonly recommended treatment is physiotherapy and bracing. Approximately 88% of the patients benefit from this combination of treatment methods. Now controversial, corticosteroid injection was once considered the gold standard in the treatment of lateral epicondylitis. However, studies show that it is merely the best treatment option in the short-term, when compared with physiotherapy and wait-and see policy. Poor results are often seen after the 12-week follow-up. Treatment with corticosteroids has a high frequency of relapse and recurrence, probably because intratendinous injection may lead to permanent adverse changes within the structure of the tendon and because patients tend to overuse the arm after injection as a result of direct pain relief. In a meta-analysis, Smidt and colleagues showed that the effects of steroid injections-as compared with placebo injection, injection with local anesthetics, injection with another

steroid, or another conservative treatment-are not significantly different in the intermediate and longterm. However, the patients who were examined all had short-term lateral epicondylitis. There are various types of surgical procedures for patients with chronic lateral epicondylitis. Verhaar and colleagues noted an improvement in 60% to 70% of the patients after surgical treatment, although higher success rates (80 to 90%) have more recently been reported. Patients remain, however, interested in an alternative to surgical intervention. Autologous biological blood that can be exogenously applied to various tissues where, after being injected, the platelet present in the blood releases high concentrations of platelet-derived growth factors that enhance tissue healing. No activation agent was used during our procedure. The activation of the platelets will occur through the exposure of platelets to the thrombin, which is released from the tendon tissue during injection. During the first 2 days of tendon healing, an inflammatory process is initiated by migration of neutrophils and, subsequently, macrophages to the degenerative tissue site. In turn, activated macrophages release multiple growth factors, including platelet-derived growth factor, transforming growth factors alpha and beta, interleukin-1, and fibroblast growth factor. Angiogenesis and fibroplasia start shortly after day 3, followed by collagen synthesis on days 3 to 5. This process leads to an early increase in tendon breaking strength, which is the most important tendon healing parameter, followed by epithelization and, ultimately, the remodeling process. This was confirmed in an animal study. The treatment of tendinosis with an injection of autologous blood may be a nonoperative alternative. Injection of autologous blood has been shown to improve repair in tendinosis in several animal and in vitro models. A possible

explanation for the long-lasting effect of platelets could be that platelets improve the early neotendon properties so that the cells are able to perceive and respond study confirm the suggested positive effect in vivo as described by Dr. Shiva Kumar Kerakkanvar, Dr. Anil Patil and Dr. Pramod Kumar M. They reported a significant improvement of symptoms after 12 weeks in 60% of the patients treated with blood versus 20% of the patients treated with a local anesthetic. After 6 months the improvement in patients treated with blood was 81%. They compared blood with a local anesthetic, which is not an accepted treatment for lateral epicondylitis in the Netherlands. Furthermore, they injected only 15 patients with blood and compared them with 5 patients treated with a local anesthetic. The study was underpowered and the patients were not randomized. Our results confirm the results of Edwards and Calandruccio. They injected whole blood into patients with lateral epicondylitis. Treatment success was seen in 79% of patients; however, multiple injections were necessary in 32% of patients. The limitation of this study is that all patients had failed previous nonsurgical treatments, including prior steroid injections. Furthermore, some patients had a beneficial effect after receiving more than 1 injection. In our study, a single percutaneous injection of blood or corticosteroid was used. Repeated injections might be beneficial in patients who had suboptimal results after the initial injection, although no evidence for a beneficial effect of more than one injection exists. In both the corticosteroid group and the blood group, each patient has a natural history to have the same influence on both group. In conclusion, this report describes the first comparison of an autologous blood with the gold standard, corticosteroid injection, as a treatment for lateral epicondylitis in patients. It demonstrates that a

single injection of autologous blood improves pain and function more so than corticosteroid injection. These improvements were sustained over time with no reported complications. Perhaps for athletes it is less optimal, but all depends on the demands of the patient.³⁻⁷

Conclusion

To conclude injection technique using steroid or autologous blood is easy and of value for the patients. Among these two, steroid injection once considered as a gold standard therapy for tennis elbow produces symptomatic relief in short times, but recurrence of the disease is problematic. Autologous blood injection produces a slow but long lasting effect and also prevents recurrence.

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