



**Original Article:**

**Autologous Blood versus Corticosteroid Local Injection for Treatment of Lateral Epicondylitis: A Randomized Clinical Trial.**

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**Abstract: Objective:** The objective of the present single blinded prospective randomized control trial was assessment of efficacy of autologous blood injection versus local steroid injection in treatment of lateral epicondylitis of elbow.

**Methodology:** Using a pre-post experimental design, a total of sixty patients of previously untreated lateral epicondylitis were selected; Group 1 (n=30) was administered single injection of autologous blood and Group 2 (n=30) single local corticosteroid injection. Assessment was done at baseline, 2 weeks, 6 weeks and 12 weeks using PRTEE (Patient Rated Tennis Elbow Evaluation) score. **Results:** Pre injection parameters showed no difference between groups (chi square test,  $p > 0.005$ ). Analysis between groups showed significant decrease in steroid group at very short term - 2 weeks (unpaired t test,  $p < 0.005$ ). There was no difference between groups at 6 weeks. There was a significant improvement in blood group at medium term -12 weeks (unpaired t test,  $p < 0.05$ ). **Conclusion:** Both the interventions were effective in reducing pain and improving functional status of patients in short term, but autologous blood was more effective in longer run.

**Key Words:** Autologous blood; Lateral epicondylitis; Steroid injection; Treatment

**Introduction:**

Lateral epicondylitis or tennis elbow is a common condition that causes pain on the lateral side of the elbow. Lateral epicondylitis is one of the most common overuse syndromes seen in primary care, with an annual incidence of 1 to 3 per cent; the condition affects men and women equally.(1) Lateral epicondylitis or epicondylitis is a painful musculoskeletal condition seen in working age group which

is due to repetitive over-use, over-stress or over-exertion of the wrist extensors of the fore-arm. The chief complaints in lateral epicondylitis are decreased grip strength, decreased functional activities, and increased pain, which may impart significant disability in activities of daily living.(2)

Diagnosis of lateral epicondylitis is straightforward but there is no consensus on treatment while efficacy of existing treatments is poor. Historically, the primary lesion in lateral epicondylitis was considered to be inflammatory granulation tissue in the tendinous portion of the origins of the forearm musculature just distal to the epicondyle of the humerus. The lesion is found primarily in the extensor carpi radialis brevis (ECRB) origin, with less frequent involvement of the extensor carpi radialis longus (ECRL) and the anterior portion of the extensor digitorum communis.(3) Therefore local steroid injections, aimed at arresting the inflammatory cascade, have given a consistent good short term pain relief, but there is no evidence that steroids promote healing.(4)

Recent studies of chronic tennis elbow have not found any significant evidence of inflammatory processes and the term epicondylitis has been suggested as a more appropriate term than epicondylitis.(5) Newer reports have shown that angiofibroblastic degeneration in the origin of ECRB is the basic cause of chronic lateral epicondylitis.(5) Recent reports have shown that local injection of autologous blood significantly helps in the healing process in tennis elbow.(6) These humoral growth factors can be given in form of whole blood or platelets concentrate injection. Presently scientific studies supporting use of these treatment methods in daily clinical practice are rare.(6,7) We have therefore compared single injection of autologous blood and steroid in a

prospective, randomised study of patients with lateral epicondylitis of elbow.

### Materials and Methods

This single blinded randomized clinical trial was conducted using pre-test post-test experimental design at Orthopaedic & Physiotherapy OPD of a tertiary Medical College, in northern India between March 2012 and September 2012. The study was approved by the ethical committee of the medical college and attached hospital.

### Participants

A total of sixty, both male (n=28) and female (n=32) patients of previously untreated lateral epicondylitis were included in the study. A detailed clinical history and clinical examination along with standard anteroposterior and lateral radiographs of involved elbow were taken in all patients. Only previously untreated patients of lateral epicondylitis and having no other identifiable cause of lateral elbow pain were included in the study.

### Procedure

After screening for inclusion and exclusion criteria the subjects were quasi randomized into two groups by alternate allocation with 30 subjects in each group. Informed written consent was obtained from all the subjects. All patients were given treatment and analysed as per study protocol.

### Intervention

Two groups were formed with one group receiving local steroid injection and the other one local injection of autologous blood. The cases were allotted to the groups on alternate basis. In Group I, 2 ml of venous blood was drawn from the upper limb and was injected after mixing with 1 ml of 2% lignocaine solution. In Group II 40 mg of depot methyl prednisolone acetate was used along with 1ml of 2% lignocaine solution. All injections were administered in the outpatient department taking aseptic precautions into the point of maximal tenderness at the extensor origin of the lateral epicondyle of the humerus by single author in all the cases. All subjects were advised to rest and moderate their activities to avoid aggravation of their symptoms.

### Measurement of outcome

Primary outcome measure was Patient-rated Tennis Elbow Evaluation [PRTEE], (100 points) assessed at baseline, 2, 6 and 12 weeks.(8) It measures three dimensions: pain, function with the affected arm and usual activities. The PRTEE consists of 15 items. All responses are rated on a visual numeric scale (VNS). This differs from the visual analogue scale (VAS) in that it is an ordinal scale as opposed to a continuous one. Respondents are asked to circle the number that best describes the situation or condition stated in the question. The numbers on the VNS are placed 1 cm apart from one another. The range of possible values is from 0 to 10, where 0 represents 'no pain' or 'no difficulty' and 10 represents 'worst pain imaginable' or 'unable to do', depending on the subscale (pain versus function/activities). The measurement tool is scored as the mean of all the items. Sub scores for each dimension are scored as the mean of all the items in each particular dimension. Higher scores indicate higher pain and/or higher dysfunction. The PRTEE is a reliable, reproducible, and sensitive instrument for assessment of lateral elbow epicondylitis.(8)

### Statistical Analysis

A pre-post experimental (parallel group) study was used for the study. The data was analysed using the SPSS 17 software. Paired t-test was used for serial analysis within the groups. Unpaired t-test was used for comparison between the groups. The test was applied at 95% confidence interval and results were taken to be significant if p<0.05. Chi square test was applied for comparisons of baseline pattern of two groups.

### Results

A total of 60 patients of unilateral untreated lateral epicondylitis were divided in two groups. Group 1 received

autologous blood and group 2 received steroid injection. Pre-test and post-test results of both groups were analysed. Table 1 shows baseline clinical and demographic data of both groups. There was no statistically significant difference between these two groups. The study also showed that the dominant upper limb was more affected- 40 elbow (66.67%).

	<b>Group 1 (n=30) Autologous blood</b>	<b>Group 2 (n=30) Steroid</b>	<b>p value</b>
Sex*(male/female)	12/18	16/14	0.1432(NS)
Laterality* (Right/Left)	19/11	21/9	0.4256(NS)
Age(in years)#	35.2 (6.84)	33 (5.68)	0.1806(NS)
Average duration of symptoms(in weeks)#	7.33 (2.49)	6.93 (3.28)	0.5967(NS)
Mean PRTEE score#	72.8 (6.97)	73.2 (8.16)	0.8389(NS)
Chi square test, #unpaired t-test, NS- not significant			

### Group 1

Baseline mean PRTEE score in patients receiving autologous blood injection was 72.8 ± 6.97 which decreased to a mean PRTEE score of 40.93 ± 5.94 after 2 weeks of injection. The mean PRTEE score at 6 week and 12 week follow up was 24.46 ± 4.58 and 14.86 ± 3.48 respectively. The mean decrease observed in PRTEE scores at 2 week, 6 week and 12 week follow up after blood was highly significant (p<0.0001).

### Group 2

The mean pre injection PRTEE score in patients receiving steroid injection was 73.20 ± 8.16. The mean PRTEE score at 2 week, 6 week and 12 week follow up was 35.60 ± 3.62, 24.53 ± 4.71 and 20.20 ± 9.88 respectively. After application of paired t test, the p value for fall in mean PRTEE score at 2, 6 and 12 weeks came out to be less than 0.0001 which was highly significant.

	Pre-treatment	At 2 weeks	At 6 weeks	At 12 weeks
Group 1 (autologous blood)	72.8 ± 6.97	40.93 ± 5.94	24.46 ± 4.58	14.86 ± 3.48
Group 2 (steroid)	73.20 ± 8.16	35.60 ± 3.62	24.53 ± 4.71	20.20 ± 9.88
P value*	0.8389	0.00009	0.9603	0.0071
Significance	NS	Significant	NS	Significant
*unpaired t test, NS – not significant				

### Data analysis between groups

The pre injection mean PRTEE score was similar in both groups. Clinically there was more pain relief and improvement in PRTEE score in steroid at weeks which was statistically highly significant (Table 2). The mean PRTEE scores at 6 weeks were similar in both groups. Comparison of mean PRTEE scores at 12 weeks showed a significant (p < 0.01) superiority of autologous blood over steroid in down staging of disease (Table 2).

### Discussion

Lateral epicondylitis or tennis elbow of the humerus has been recognised for over 100 years and is an enthesopathy of the common extensor origin. The term tennis elbow is also not suitable as it is common in occupations involving repetitive forearm movements. In our series none of the patients were tennis player. Among the patients, majority (32 patients-

53.3%) were female; and 80% were housewives, implying the high prevalence of lateral epicondylitis among women doing daily household chores. Historically, an acute inflammatory response is thought to be responsible for the disorder (5), suggesting that treatments should focus on the resolution of inflammation. However, more recent histopathological examinations suggest that a non-inflammatory degeneration of extensor carpi radialis brevis is present and Lateral epicondylitis is a more suitable term to describe the condition. (9) Therefore treatments should be aimed at normal vascularisation and healing in the affected tendon.(7)

The optimal treatment for lateral epicondylitis of elbow has still not been determined. Conservative management consisting of activity restriction, splints and orthotics, non-steroidal anti-inflammatory drugs and physiotherapy are the first line of management. Local corticosteroid injection is the commonest treatment given in cases where conservative management fails. Tonks et al. have demonstrated that local steroid injection is the best initial treatment for lateral epicondylitis of the elbow.(4) A recent Cochrane review has concluded greater benefit from glucocorticoid injection in the short term; although it yielded poor results in long term (1 year) follow up in comparison to physiotherapy.(10) Other modalities such as prolotherapy, topical nitroglycerin, iontophoresis, phonophoresis, therapeutic ultrasound, extracorporeal shock wave therapy, and low-level laser therapy have less evidence of effectiveness in treatment of tendinopathies.(11)

Recent studies show a beneficial role of locally delivered biological growth factors in healing of various tendinopathies. This can be achieved in form of autologous blood, platelet rich plasma [PRP] or bone marrow concentrate. A recent study by Harmon et al has shown that biologic therapies such as autologous blood and PRP injection are effective treatment for recalcitrant tendinopathy, and PRP appears to be more effective than autologous blood. (12) Similarly, Moon et al have demonstrated the injection of iliac bone marrow plasma in severe elbow tendinosis demonstrated early recovery of daily activities and clear improvement (13).

The results of our study showed that corticosteroid injection is superior to autologous blood in terms of clinical improvement in very short term (at two weeks follow up). This is in confirmation with previous studies that steroid injection give earliest pain relief.(4,10,14) Comparison between the two groups showed similar improvement in PRTEE scores at short term (6 weeks). Statistical analysis revealed that autologous blood was superior to steroid injection in medium term follow up (at 12 weeks) of lateral epicondylitis patients in terms of down staging and healing. This result is in direct consistency with study of Nicola Massy-Westropp et al.(15) Edwards et al also reported in their trial, that autologous blood is superior to local steroid injection in medium to long term follow up.(6)

Mechanism of action of biological therapies, including autologous blood, PRP and bone marrow concentrate, is attributed to degranulation of a granule of platelets releasing growth factors responsible for tissue healing and regeneration. Platelet derived growth factor, transforming growth factor  $\beta$ , vascular derived endothelial growth factor, epithelial growth factor, hepatocyte growth factor and insulin like growth factor are some of the factors involved.(17) Preparation of PRP and bone marrow concentrate require specialized equipment which is time consuming and expensive. Autologous blood injection is an inexpensive modality which can be easily used in clinical settings.

One major limitation of our study is absence of long follow up. Long term follow up is required to see the sustained effect of autologous blood injection in terms of pain relief

and healing of disease. We have chosen a follow up only up to 12 weeks as improvement in symptoms after this period may be a result of natural healing process and activity modification by patients. Further studies are required to standardize the dose, number and timing of autologous blood injection for treating lateral epicondylitis of elbow.

### Conclusion

Our clinical findings suggest that the use of single autologous blood injection is an effective solution for degenerative lateral epicondylitis of elbow. It offers significant better outcome over steroid injection in medium term follow up

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