



A Prospective Randomized Control Study Comparing Efficacy of Platelet Rich Plasma Injection with Local Corticosteroid Injection in Patients of Lateral Epicondylitis

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Abstract

Background: Lateral epicondylitis of humerus, or tennis elbow, is a commonly encountered problem in orthopaedic practice. The specific goal of the present study was to measure the efficacy of PRP as a potential new treatment for lateral epicondylitis and comparing it with local corticosteroid injection.

Material & Methods: 25 cases and 25 controls were selected. Cases were injected with intralesional Platelet Rich Plasma Injection and controls were injected with local Corticosteroid injection at lateral epicondyle. Participants were followed-up for total of 6 months. Follow up period was divided in to intervals of 4th week, 8th week and 6 months. Outcome was measured using 'Visual Analog score' and 'MMCPI of lateral epicondylitis'.

Results: At the end of 6 months 44% patients in corticosteroid injection group and 88% patients in Platelet Rich Plasma Injection group were completely relieved of pain. P value for VAS Score was 0.01208 and P value for MMCPI was 0.01314 which were statistically significant. Hence at 6 month the decrease in pain was statistically significant in Platelet Rich Plasma Injection group compared to corticosteroid injection group.

Conclusion: In this study Platelet Rich Plasma Injection demonstrated a statistically significant decrease in pain compared to corticosteroid injection group even on long term follow up (6 months).

Keywords: Lateral epicondylitis; Tennis elbow; Platelet Rich Plasma (PRP); Corticosteroid; Visual Analogue Scale

Introduction

Lateral epicondylitis of humerus, or tennis elbow, is a commonly encountered problem in orthopaedic practice. It has been found to be the second most frequently diagnosed musculoskeletal disorder in the neck and upper extremity in a primary care setting.¹

It has an incidence of 4-7 per 1000 patients per year in general practice, with a peak between the ages of 35 and 54 years, with a mean age of approximately 42 years.^{2,3,4} Various findings have been reported in the literature with respect to gender prevalence,

however no distinct prevalence is evident.^{4,5} The dominant arm has been found to be predisposed to lateral epicondylitis. In a study 87% of the cases have dominant arm involvement.⁶

Currently degeneration of the origin of the extensor carpi radialis brevis muscle (ECRB), repeated micro trauma and incomplete healing response has been accepted as the cause of lateral epicondylitis by most of the researchers.¹⁰

Histopathological reports have shown that lateral epicondylitis is not an inflammatory process but a degenerative condition termed 'tendinosis'.^{9,10,11}

Even though it has been termed tennis elbow and called same routinely, it is seen to affect non-athletes more than athletes.^{7,8}

Most conservative modalities such as local corticosteroid injection have focused on suppressing inflammatory process that does not actually exist. A recent review article concluded that for short term outcomes (< 6 weeks), statistically significant and clinically relevant differences were found on pain and global improvement with corticosteroid injection compared to placebo, local anaesthetic, or other conservative treatments.¹² For intermediate (6 weeks to 6 months) and long term outcomes (more than 6 months), no statistically significant or clinically relevant results in favour of corticosteroid injections were found. So it is not possible to draw a firm conclusion on the effectiveness of corticosteroid injection.^{12,13,14,15}

Recently an injection of autologous blood has been reported to be effective for both intermediate and long term outcomes for the treatment of lateral epicondylitis. There was a significant decrease in pain.^{9,11,16}

Platelet Rich Plasma (PRP) is a bioactive component of whole blood. PRP, in general, has a higher concentration of platelets compared with baseline blood. Clinically valuable PRP, however contains 1 million platelets or more per microliter. Studies have shown that clinical efficacy can be expected with a minimum increase in platelet concentration of 4- to 6-fold from whole blood baseline (1 million platelets/ μ l).^{27, 28}

Exogenous growth factors (Iwaski M et al., 1995)¹⁷ to an injured tendon can enhance healing and repair. One possible method of introducing an assortment of growth factors to an area of tendinopathy is through the injection of platelet rich plasma (Mishra et al 2006)²⁴ or autologous blood (Edward SG et al 2003)⁹. Platelet-rich plasma contains a more concentrated amount of platelets than does whole blood. Within platelets are powerful growth factors (Iwaski M et al., 1995)¹⁷, including platelet-derived growth factor (PDGF), transforming growth factor beta (TGF β 1 & TGF β 2), insulin like growth factor (IGF) and

epidermal growth factor. When platelets are activated either ex vivo or in vivo, they release the growth factors and proteins that reside within their alpha granules.

There are very few studies done to evaluate injection of autologous blood for lateral epicondylitis as treatment modality. Hence it is evaluated by comparing with the corticosteroid injection which is a commonly practiced conservative treatment modality.^{8,15,18,19,20}

The specific goal of the present study was to measure the efficacy of PRP as a potential new treatment for lateral epicondylitis and comparing it with local corticosteroid injection.

Aims And Objectives

1. To establish the role of platelet rich plasma for the treatment of lateral epicondylitis.
2. To compare the effect of PRP and corticosteroid, for the treatment of lateral epicondylitis.
3. To study any complications associated with the PRP therapy, if any.

Material And Methods

Injection of platelet rich plasma was independent variable and pain at lateral epicondyle was dependent variable.

Source Of Data

All confirmed patients of lateral epicondylitis willing for the treatment attending our tertiary care hospital.

Methods Of Collection Of Data

1. By interview & examination
2. By follow-up of total 6 months. It was divided into intervals at 4week, 8 week and 6 month.
3. Sample size: The randomized control trial was a pilot study, so 25 cases and 25 controls were selected.
4. Study design: Randomized control trial comparing the efficacy of Platelet Rich Plasma Injection with local corticosteroid injection.

Consent was taken from the participants. Cases were injected with intralesional Platelet Rich Plasma Injection and controls were injected with local Corticosteroid injection at lateral epicondyle.

Inclusion Criteria:

1. Clinically diagnosed lateral epicondylitis (based on symptoms, site of tenderness, and pain elicited with resisted active extension of the wrist in pronation and elbow extension),
2. No history of trauma,
3. Duration equal to or more than 3 months with at least 60 of 100 on a visual analogue score
4. (0, no pain; 100, maximum pain possible)
5. No previous local injection treatment of any kind,
6. No medical history of rheumatic disorder, diabetes, cervical radiculopathy and carpal
7. tunnel syndrome
5. No signs of posterior interosseous nerve entrapment.
6. No bleeding disorder, not on anti coagulation medication, not having cancer, active
8. infection and non-pregnant.

Exclusion Criteria:

1. Pregnancy, history of carpal tunnel syndrome, cervical radiculopathy, and systemic disorders such as diabetes, rheumatoid arthritis, and hepatitis.
2. Onset of symptoms (<3 months),
3. History of trauma,
4. Previous local steroid injections
5. Other causes of elbow pain such as osteochondritis dessicans of capitellum, lateral compartment arthrosis, varus instability, radial head arthritis, posterior interosseous nerve syndrome, cervical disc syndrome, synovitis of radiohumeral joint, cervical radiculopathy, fibromyalgia, Osteoarthritis of elbow, Carpel tunnel syndrome.

Group A (n=25) : Patients received an injection of PRP.

Group B (n=25) : The control patients 25 in number received an injection of

Corticosteroid.

Procedure:

Group A: PRP Injection group

Thirty millilitres of venous blood was collected from the uninvolved arm and transferred to three 10 ml EDTA coated vacutainer tubes. A peripheral complete blood count was also being done at the time

of the initial blood draw to determine the initial platelet count. The samples were gently agitated to thoroughly mix the anticoagulant with the blood. The blood sample was then centrifuged for 15 mins at 3200 rpm resulting in the three following layers: the inferior layer composed of erythrocytes, the intermediate layer composed of leukocytes, and the superior layer made up of plasma. The buffy coat layer together with the plasma layer was collected and centrifuged for another 10 mins at 1500 rpm to separate the leukocytes. The plasma layer was collected, and the third centrifugation step at 3200 rpm for 10 mins was performed to obtain a two-part plasma: the upper part consisting of platelet poor plasma and the lower part consisting of PRP. The platelet-poor plasma was first discarded to avoid its mixing up with the PRP. The tubes were shaken vigorously for 30 secs to suspend platelets. The buffy coat layer, consisting of platelets, was then gently aspirated into a syringe in a volume of 4 ml of plasma, which is PRP. An aliquot of product was sent to the laboratory for analysis of platelet concentration.²⁶

All the procedures were performed in the same office setting. No activating agent (calcium chloride and thrombin) was used. This 4 ml of PRP was used for local injection into the patient according to below mentioned technique.

By above method we achieved average about 5-fold increase in platelet concentration over baseline platelet count.

Group B: Local corticosteroid group

Patients were infiltrated with 80mg. of local corticosteroid (Methyl prednisolone acetate, depomedrol), at the lateral epicondyle according to the below mentioned technique.

Injection Technique:

The elbow was flexed to 90° with the palm facing down. Procedure: With patient in supine or sitting posture, elbow was painted and draped. The bony anatomical landmarks were identified. The elbow was flexed to 90° with the palm facing down. The needle introduced proximal to the lateral epicondyle along the supracondylar ridge and gently advanced in to the under surface of the extensor carpi radialis brevis, injection was injected using a 22-g needle into the common extensor tendon using a peppering

technique. This technique involves a single skin portal and then 5 penetrations of the tendon. And then a small adhesive sterile dressing was kept at the injection site, which was advised to be removed after 2 days. Patients were advised to give rest to the upper limb for 3 days. And after that no restriction of activity is advised.

Initially, 2ml of 2% xylocaine was infiltrated into the skin and subcutaneous tissue of both groups as a local field block.

Outcome Evaluation

Outcome was measured using ‘Visual Analogue Scale’ and ‘MMCPI’ for elbow.^{6,24}

Outcome Measures:

Pain score; Visual Analogue Scale:

Pain of the participants was assessed by most widely used and accepted “visual analogue scale”. It consists of a 100 centimeter line marked at one end with “no pain” and at other end with “worst pain ever”. Participants were asked to indicate where on the line he or she rates the pain on the day of presentation, 4, 8 weeks and 6 month of follow-ups. Numerical value was then given to it simply by measuring length between “no pain” to patient’s mark.

No pain___10___20___30___40___50___60
 _____70___80___90___100 worst pain ever.

Modified Mayo Clinic Performance Index for the Elbow

Mayo Index	Points
Parameter/findings	
Pain	
None	45
Minimal	37.5
Mild	30
Moderate	15
Severe	0
Motion	
Full motion	20
Stability	
No clinical laxity	10
Daily function/performance	
Combing hair	
Able	5
Able with pain	2.5

Unable	0
Eating	
Able	5
Able with pain	2.5
Unable	0
Hygiene	
Able	5
Able with pain	2.5
Unable	0
Dressing	
Clothing	5
Able	2.5
Able with pain	0
Unable	
Shoes and socks	5
Able	2.5
Able with pain	0
Unable	

Interpretation

Excellent >90

Good 75-89

Fair 60-74

Poor <60

Statistical test: Mann-Whitney U test (non parametric test), ‘t’-test and Chi-square test were applied to calculate the significance of results. Two groups were statistically compared.

Results And Obsrvations:

Procedure was done in 50 patients under the present study. Participants were clinically evaluated. A baseline VAS scores and MMCPI for the pain at lateral epicondyle was recorded. Cases were treated with local Platelet Rich Plasma Injection and controls with local corticosteroid injection. After the procedure patients were asked to report immediately if any increase in pain was there and were asked to follow up at 4 weeks, 8 weeks and 6

months interval after the injection. If pain persisted analgesics were given and was advised to be taken only if there is unbearable pain.

The severity of pain during the day at baseline and during followup at 4 weeks, 8 weeks and 6 months

Table 01: Mean VAS score for the two groups

Follow-up period	Local corticosteroid injection		PRP injection		p Value	Inference
	Mean VAS Score	S.D.	Mean VAS Score	S.D.		
Before injection	74.8	12.29	78	13.54	0.27572	N.S.
4 weeks	15.2	23.83	32.4	26.03	0.0088	S
8 weeks	16	18.93	7.2	20.72	0.02642	S
6 month	20	21.21	6.4	20.79	0.01208	S

Graph 01: Mean VAS score for the two groups

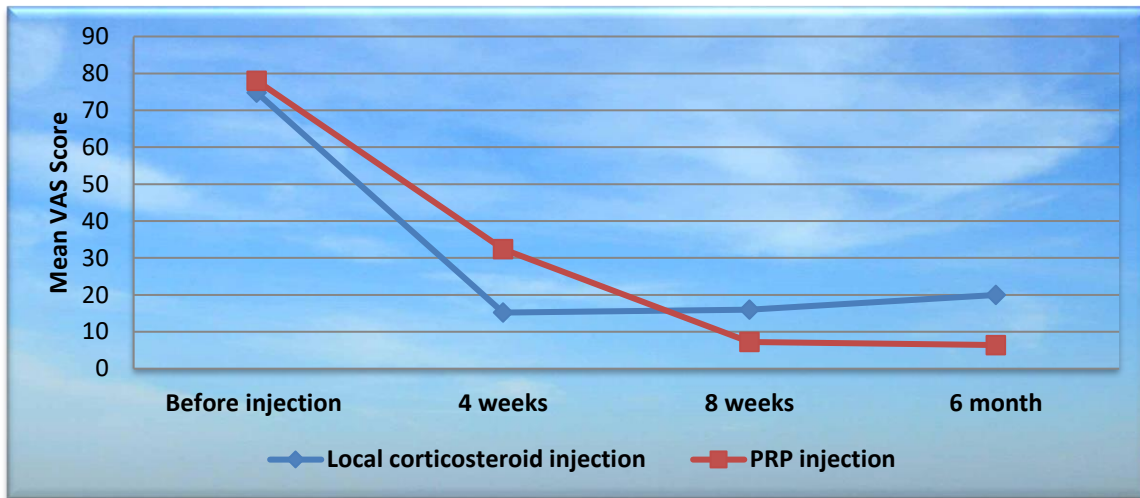


Table 02: Mean MMCPI for the two groups

Follow-up period	Local corticosteroid injection		PRP injection		p Value	Inference
	Mean MMCPI	S.D.	Mean MMCPI	S.D.		
Before injection	53	10	50.2	11.59	0.31732	N.S.

4 weeks	91.8	14.06	81.2	16.41	0.00634	S
8 weeks	91.6	12.22	95.8	12.39	0.03752	S
6 month	89.2	12.96	96.2	12.44	0.01314	S

Graph 02: Mean MMCPI for the two groups

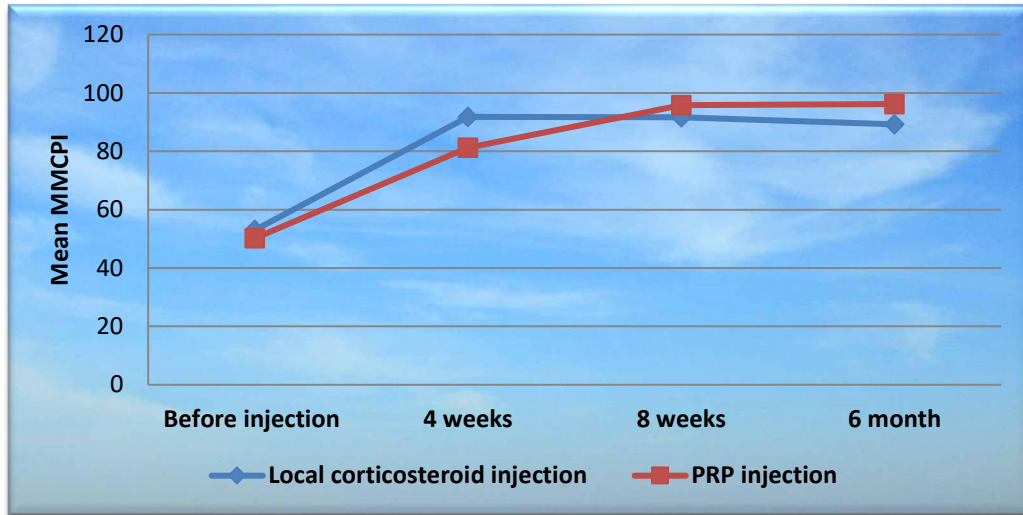
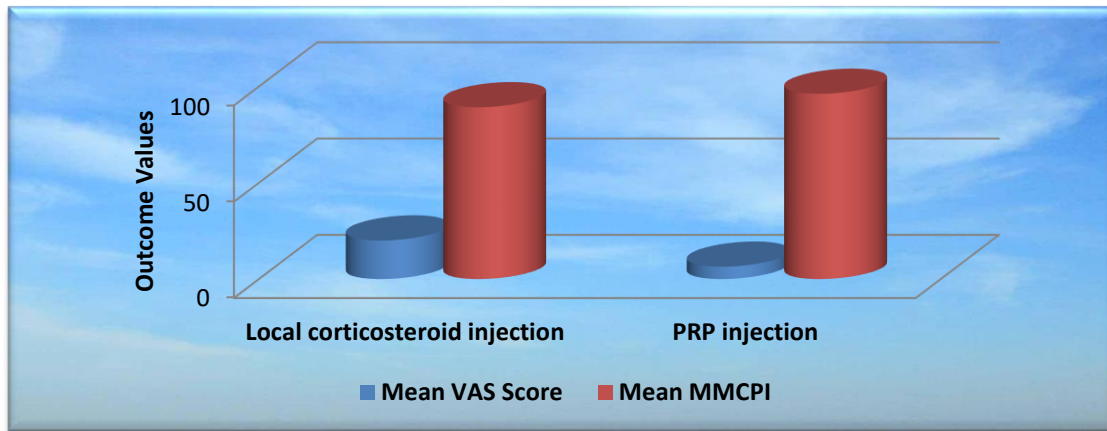


Table 03: Outcome measures at 6 months

	Local corticosteroid injection	PRP injection	P Value	Inference
Mean VAS Score	20	6.4	0.01208	S
S.D.	21.21	20.79		
Mean MMCPI	89.2	96.2	0.01314	S
S.D.	12.96	12.44		

P value for VAS Score was 0.01208 and P value for MMCPI was 0.01314 which were statistically significant. Hence at 6 month the decrease in pain was statistically significant in Platelet Rich Plasma Injection group compared to corticosteroid injection group.

Graph 03: Outcome measures at 6 months



Discussion

Tennis Elbow is a common problem encountered in orthopaedic practice and general Practice. Majority of the treatment modalities used for its management lack scientific rationale.¹⁴ The role of local steroid is debatable.

Recently an injection of Platelet Rich Plasma has been reported to be effective for both intermediate and long term outcomes for the treatment of lateral epicondylitis. There was a significant decrease in pain.^{3, 16, 24} It is hypothesized that mitogens such as platelet derived growth factor induce fibroblastic mitosis and chemotactic polypeptides such as transforming growth factor cause fibroblasts to migrate and specialize and have been found to cause angiogenesis. A specific humoral mediator may promote the healing cascade in the treatment of tendinosis as well. These growth factors trigger stem cell recruitment, increase local vascularity and directly stimulate the production of collagen by tendon sheath fibroblasts.¹⁷

In this current study, the mean age encountered was 42.7 years (Range: 17 to 67 years); the peak incidence was seen from 35 to 50 years. This was seen similar in two separate studies which observed mean age of 45 and 43 years.^{21, 25} Another study observed the mean age to be 46.5 years.⁹

In this current study, out of the 50 participants, 21 (42%) were male patients and 29 (58%) were female patients. Two other studies had more number of male patients.^{23, 21, 25} one more study had equal number of males and female patients.¹⁰ Contrary to other

studies more number of female patients in this current study may be due to that, females at this study area were more involved with household work which causes repetitive stress at the extensor carpi radialis brevis origin causing micro trauma, a relevant etiology for the initiation of the disease.

In this current study, out of the 50 participants, 36 (72%) participants had their right side elbow affected and 14 (28%) had their left side affected. Out of the 50 participants, 40(80%) participants had their Dominant elbow affected and 10(20%) had their Nondominant elbow affected. In other two studies, one had 84% of the patients with their dominant elbow affected, while in another 78.6% of the patients with their dominant side affected.^{25, 9}

Parameters like age, sex, side of elbow involved, dominance of upper limb involved, duration of symptom and type of occupation of the patients were comparable. The mean VAS score and MMCPi before injection in both the groups were comparable. Mean VAS score for steroid injection group was 74.8, mean VAS score for Platelet Rich Plasma Injection group was 78, P value was 0.27572; mean MMCPi for steroid injection group was 53, mean MMCPi for Platelet Rich Plasma Injection group was 50.2, P value was 0.31732.

Till 4 weeks follow up, statistically significant difference between the two groups with VAS scoring and MMCPi was seen. Corticosteroid injection group showed statistically significant decrease in VAS score and increase in MMCPi at 4th week compared to Platelet Rich Plasma Injection group. One study

showed similar results with local corticosteroid injection group, when compared with oral naproxen.²³

At 8th week and at 6 month follow up (Table 1, 2, 3 and Graph 1, 2, 3) Platelet Rich Plasma Injection group showed statistically significant decrease in VAS score and increase in MMCPi compared to corticosteroid group. At 6 months follow up, mean VAS score for steroid injection group was 20, mean VAS score for Platelet Rich Plasma Injection group was 6.4, P value was 0.01208; mean MMCPi for steroid injection group was 89.2, mean MMCPi for Platelet Rich Plasma Injection group was 96.2, P value was 0.01314.

At the end of 6 months 44% patients in corticosteroid injection group and 88% patients in Platelet Rich Plasma Injection group were completely relieved of pain. This was highly statistically significant with a P value of 0.002836.

One study reported that 22/28 patients (79%) responded to Autologous Blood Injections with average Nirschl Scores decreasing from 6.5 to 2.0 with a mean follow up of 9.5 months.⁹

In Corticosteroid injection group till 4 weeks there was significant improvement with 64% of patients completely relieved of pain. Many of these patients reported recurrences at 8 weeks and 6 month follow up. The rate of recurrence was 37.5% in corticosteroid injection group. Similar recurrence rate was seen in one study where 14% patients worsened in their symptoms with corticosteroid injection.²³

In Platelet Rich Plasma Injection group at 4th week follow up, 20% of patients were completely free of pain. At the end of 6 months there was no recurrence.

Maximum benefit reached at an average of 5.24 weeks in corticosteroid injection group. Maximum benefit reached at an average of 8.92 weeks in Platelet Rich Plasma Injection group. This was statistically significant with a P value of 0.00116.

This study cannot prove conclusively whether the blood itself induced an inflammatory cascade or whether the injury created by the injection was responsible. It is theorized that the beneficial effects of steroid injection result from the bleeding caused by forcing fluid through tissue planes at high pressures.²²

It was seen that there was a significant increase in post intervention pain for few days in Platelet Rich Plasma Injection group. In corticosteroid injection group 7 participants (28%) patients complained of post-intervention exacerbation of pain while in Platelet Rich Plasma injection group 15 participants (60%) complained of increase of pain after local injection. This was statistically significant with a p value of 0.022654.

In this current study it was seen that in PRP group, mean platelet concentration in whole blood was about $263.48 \times 10^3/\mu\text{l}$ and mean platelet concentration in PRP was about $1320.84 \times 10^3/\mu\text{l}$. Another study had shown that clinical efficacy can be expected with a minimum increase in platelet concentration of 4- to 6-fold from whole blood baseline (1 million platelets/ μl).^{27,28} By our method we achieved average 5 fold increase in platelet concentration over baseline platelet count.

And these patients had to be managed with oral analgesics for varying period of days (2 to 7 days) for pain relief.

To conclude, Platelet Rich Plasma Injection was beneficial both in short term and long term for the treatment of lateral epicondylitis. Advantages of Platelet Rich Plasma Injection are-highly acceptable, efficacious, economic, easy to carry out as outpatient procedure, devoid of potential complications such as hypoglycaemia, skin atrophy, tendon tears associated with corticosteroid injection and low recurrence rate.

Clinical findings such as those presented should be correlated with histologic specimens showing evidence of healing such as organization of collagen bundles and return to normal cellular activity after injections of Platelet Rich Plasma into areas of tendinosis. The subject bias inherent in the design of our study was unavoidable because it was difficult to blind either patient or investigator in regard to drawing autologous blood and injecting Platelet Rich Plasma. Furthermore most patients were reluctant to donate blood that may be discarded and not used for their benefit. Nonetheless this study offers encouraging results of an alternative treatment that addresses the pathophysiology of lateral epicondylitis that had failed traditional nonsurgical modalities. Further clinical studies may prompt other investigators to further define substances that may

enhance tendon healing for lateral epicondylitis and other disabling tendinosis.

Conclusion

Lateral epicondylitis, is a common problem encountered in the orthopaedic practice.

Corticosteroid injection is associated with high recurrence on long term follow-ups.

In this study Platelet Rich Plasma Injection demonstrated a statistically significant decrease in pain compared to corticosteroid injection group even on long term follow up (6 months).

Platelet Rich Plasma Injection technique for lateral epicondylitis offers a better treatment with (1) its application is minimally traumatic, (2) it has a reduced risk for immune-mediated rejection, devoid of potential complications such as hypoglycaemia, skin atrophy, tendon tears associated with corticosteroid injection, (3) it is simple to acquire and prepare, easy to carry out as outpatient procedure and (4) it is inexpensive, (5) better relief of pain, (6) low recurrence rate.

This study offers encouraging results of an alternative treatment that addresses the pathophysiology of lateral epicondylitis that has failed traditional nonsurgical modalities.

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