

COMPARATIVE STUDY OF PLATELET RICH PLASMA (PRP) VERSUS CORTICOSTEROID INJECTION IN FUNCTIONAL OUTCOME OF CHRONIC LATERAL EPICONDYLITIS – A HOSPITAL BASED RANDOMISED TRIAL

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Abstract

Background: Lateral epicondylitis usually occurs in 1% to 3% of the general population. In patients who had failed conservative treatment, local injections of PRP, corticosteroids can be used. Many studies have used Platelet rich plasma and corticosteroids but there is area of debate over efficacy of one drug over other Hence this created a profound interest to carry out this study. **Materials and Methods:** A hospital based randomized controlled trial the study was conducted in 60 patients with a follow up period of 6 months for each patient. Patients were divided based on Block randomization. Patients were assessed for their pain and functional outcomes based on VAS and PRTEE scores at each visit. **Result:** Patients injected with PRP showed delayed outcomes on pain and functional score improvement whereas the steroid treated Group showed immediate improvement in pain and functional score. Recurrence was noted in one patient treated with steroid after 4 months. Both groups favoured beneficial to patients with some adverse effects on both groups. **Conclusion:** Both PRP and Methyl prednisolone are beneficial in treatment for lateral epicondylitis. However, no drug was found to be superior over the other based on the outcomes at final follow up.

INTRODUCTION

Tennis elbow, also known as lateral epicondylitis, is a common affliction in tennis players, cricketers, manual laborers, and vibrating tool handlers. Tennis elbow has a prevalence of 1 to 3 percent in the general population, with the peak being in the 50-60 years of age.^[1]

The extensor origin of the lateral humeral condyle is where eccentric overload and repetitive micro trauma occur, which is the main cause of the disease. ECRB and ECRL are major muscles found to exhibit this condition.^[2]

Both inflammatory and degenerative causes of lateral epicondylitis can cause abnormal collagen proliferation, resulting in structural failure and wear.^[3]

Non-operative management, mainly analgesics and physiotherapy, and life style modification are the mainstay of treatment.

Failed conservative management may requires biologicals or steroid injections

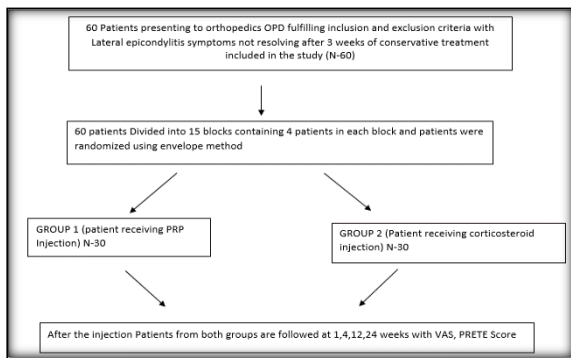
The role of corticosteroids injections is significant due to their promising results in short-term pain relief and functional outcomes. However, it is susceptible

to complications such as tendon degeneration during long-term use. Recently, PRP injections have emerged in the market as they are biological and do not have any immunogenic reactions. Studies have demonstrated that PRPs are superior to steroid injections when it comes to pain and functional outcomes.^[4] However, we need studies with longer follow up needed to find exact efficacy of PRP injections.^[5]

Other operating methods include dry needle, arthroscopic release and open debridement that has its own drawbacks in terms of costs and surgical complications. Even though there are multiple treatment options, there is no stand-alone method for managing lateral epicondylitis that provides better results. We conducted a hospital based randomized study to compare the benefits and drawbacks of PRP and corticosteroid injections.

MATERIALS AND METHODS

We conducted hospital based Randomized control trial in tertiary hospital between 2018-2020 After obtaining institutional ethical clearance.



Patients aged above 18 years presenting to orthopedic Out Patient Department (OPD) with lateral epicondylitis not resolving after 3 weeks of conservative management are included in our study. A patient with Cervical radiculopathy, Rheumatoid arthritis, previous surgery due to trauma, previous injection for lateral epicondylitis, Bleeding and clotting disorders and patients on anti-platelets and anticoagulant drugs are excluded from the study. Informed consent was obtained from all patients.

PRP Preparation: In our study for preparation PRP we used DIGITAL 8R DERMAFUGE Centrifuge machine [Figure 1]. 22 ml of patient's whole blood is drawn in with a sterile syringe. About 2ml of blood is sent for base line cell count for RBC, WBC, hematocrit and platelets. The remaining 20 ml of withdrawn blood is transferred to sterile conical tube containing 5ml of acid citrate dextrose [Figure 2] which is centrifuged at 1500 rpm for 10 minutes in the first spin (soft spin). The top layer of plasma with buffy coat obtained following the first spin is separated using a micropipette and then transferred to the second tube for centrifuge at 3500 rpm for 10 minutes (hard spin). Following the second spin the platelet erythrocyte is seen as soft pellets at the bottom of the tube with platelet poor plasma on the top. The upper 2/3 of this platelet poor plasma is discarded. The remaining 1/3 of the platelet poor plasma along with the soft pellets at the bottom of the tube is shaken to form a homogenized PRP.

Injection Technique: Under sterile aseptic precaution 2ml of activated autologous PRP or 2ml of Methyl prednisolone (40mg) injected at the maximum tender point over lateral epicondyle (fig3 &4). Patients are observed for 15 mins for adverse and allergic reactions and advised not to massage over the injection site.

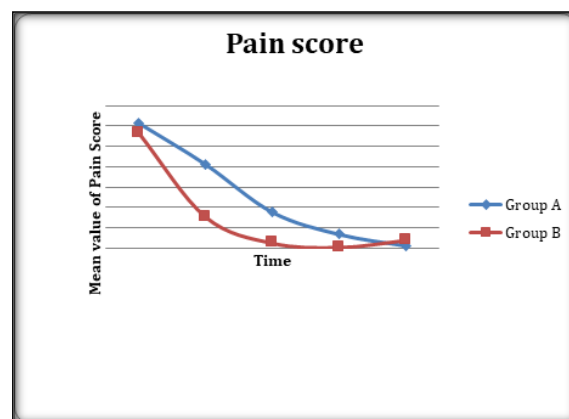
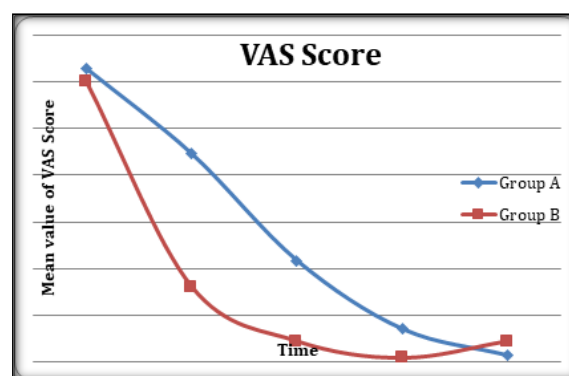
RESULTS

The age and gender distribution among the 2 groups are comparable.

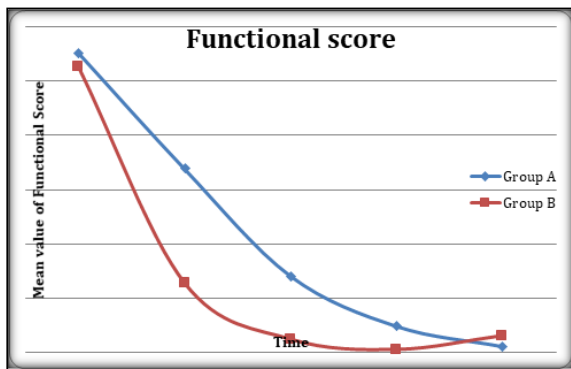
The outcome measurement following injection is measured by VAS and PRETE Scores. This numerical variable is being summarized as mean/standard deviation for normal distribution and median/ IQR for skewed distributed data respectively.

The comparison of the numerical values between the two intervention groups was done using independent t test for normally distributed data and Mann-Whitney U test for skewed data.

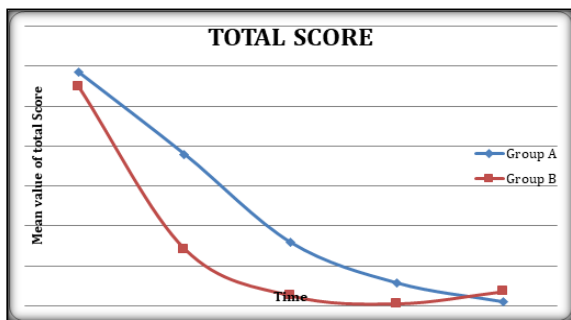
The median VAS scores among the GROUP A (PRP) group during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks were 6,5,2,0 and 0. In GROUP B (corticosteroid injection group), the median VAS scores were 6, 2,0,0,0 during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks. The comparison yielded only significant p values at 1, 4 and 12 week timelines. The VAS score was significantly lower in the corticosteroid injection group at these timelines in comparison with the platelet rich plasma (PRP) group. (As shown in Table and figure). The mean vas score of steroid group slightly higher at 24 weeks compared to PRP group but it was not statistically significant.



The median pain scores among the GROUP A (PRP) group during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks were 30,20,7,3 and 0. In GROUP B (corticosteroid injection group), the median pain scores were 30, 5.5,0,0,0 during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks. The comparison yielded only significant p values at 1, 4 and 12 week timelines. The pain score was significantly lower in the corticosteroid injection group at these timelines in comparison with the platelet rich plasma (PRP) group. (As shown in Table and figure). The mean pain score of steroid group slightly higher at 24 weeks compared to PRP group but it was not statistically significant.



The median functional scores among the GROUP A (PRP) group during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks were 27.5, 16, 6, 2 and 0. In GROUP B (corticosteroid injection group), the median functional scores were 26, 4, 0, 0, 0 during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks. The comparison yielded only significant p values at 1, 4 and 12 week timelines. The functional score was significantly lower in the corticosteroid injection group at these timelines in comparison with the platelet rich plasma (PRP) group. (As shown in Table and figure). The mean functional score of steroid group slightly higher at 24 weeks compared to PRP group but it was not statistically significant



The median total scores among the GROUP A (PRP) group during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks were 57.25, 36.5, 13.5 and 0. In GROUP B (corticosteroid injection group), the median total scores were 55.5, 9.75, 0, 0, 0 during pre-procedure, 1 week, 4 weeks, 12 weeks and 24 weeks. The comparison yielded only significant p values at 1, 4 and 12 week timelines. The total score was significantly lower in the corticosteroid injection group at these timelines in comparison with the platelet rich plasma (PRP) group. (As shown in Table and figure). The mean total score of steroid group slightly higher at 24 weeks compared to PRP group but it was not statistically significant.



Figure 1: DermaFuge Centrifuge Machine used for PRP preparation

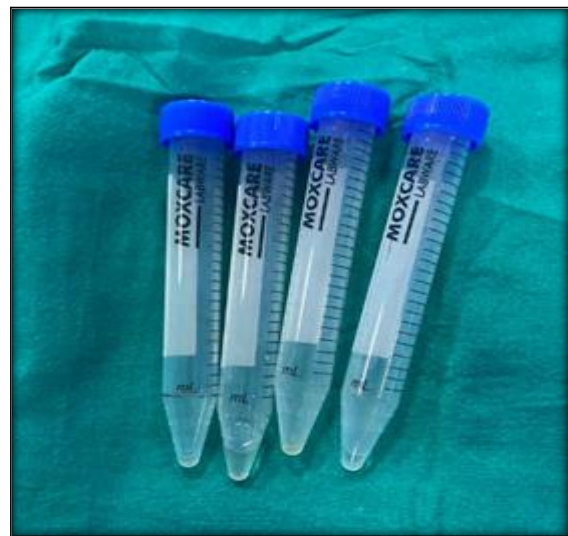


Figure 2: Conical tubes used for Sample collection and PRP Preparation



Figure 3 showing PRP Injection into the most tender point over Lateral Epicondyle



Figure 4: showing Methyl Prednisolone Injection into the most tender point over Lateral Epicondyle

Table 1: The comparison of VAS score between the 2 groups at serial interval

Time	VAS Score				P value
	GROUP A (PRP)		Group B(STEROID)		
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
Pre procedure	6.33±1.29	6, (5,7)	6±1.11	6 (5, 6.75)	0.341
At 1 week	4.47±1.28	5 (3, 5)	1.6±1.33	2 (0, 2)	<0.0001
At 4 weeks	2.17±0.95	2 (2, 3)	0.43±0.63	0 (0, 1)	<0.0001
At 12 weeks	0.7±0.88	0 (0, 1)	0.07±0.25	0 (0, 0)	0.004
At 24 weeks	0.13±0.35	0 (0, 0)	0.43±1.25	0 (0, 0)	0.932

P value calculated by Mann-Whitney U test

Table 2: Comparison of the pain score between the 2 groups at serial interval

Time	Pain Score				P value
	Group A		Group B		
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
Pre procedure	30.83±5.95	30 (28, 33.5)	28.47±7.08	30 (26, 33.75)	0.362
At 1 week	20.67±4.87	20 (18, 22.75)	7.77±6.87	5.5 (3, 12.75)	<0.0001
At 4 weeks	8.87±5.02	7 (6, 10)	1.3±1.93	0 (0, 2.75)	<0.0001
At 12 weeks	3.4±3.11	3 (2, 4)	0.23±0.73	0 (0, 0)	<0.0001
At 24 weeks	0.57±1.19	0 (0, 0)	2±6.25	0 (0, 0)	0.764

Table 3: Comparison of the functional score between the 2 groups at serial interval

Time	Functional Score				P value
	Group A		Group B		
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
Pre procedure	27.6±5.67	27.5, (24.5, 31.75)	26.27±6.46	26 (22.75, 29)	0.287
At 1 week	16.92±4.35	16 (13.25, 19.12)	6.35±5.84	4.5 (2, 10)	<0.0001
At 4 weeks	7.03±3.67	6 (4.62, 8)	1.17±1.74	0 (0, 2)	<0.0001
At 12 weeks	2.4±2.21	2 (0.62, 3.87)	0.22±0.69	0 (0, 0)	<0.0001
At 24 weeks	0.53±1.07	0 (0, 0)	1.5±4.17	0 (0, 0)	0.776

Table 4: Comparison of the Total score between the 2 groups at serial interval

Time	Total Score				P value
	Group A		Group B		
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
Pre procedure	58.43±10.82	57.25 (53.12, 64.75)	54.77±11.78	55.5 (48, 61.75)	0.304
At 1 week	37.92±8.55	36.5 (32.12, 40)	14.13±12.55	9.75 (5, 25.25)	<0.0001
At 4 weeks	15.9±8.55	13 (10.5, 17.87)	2.47±3.63	0 (0, 5)	<0.0001
At 12 weeks	5.8±5.22	5 (2.62, 7.75)	0.45±1.38	0 (0, 0)	<0.0001
At 24 weeks	1.1±2.23	0 (0, 0)	3.5±10.36	0 (0, 0)	0.770

DISCUSSION

Lateral epicondylitis (tennis elbow) is a tendinopathy of a common extensor origin mainly in the ECRB and ECRL muscles. Its chronic condition and the patient experiences pain mainly due to micro tears in the ECRB muscle and subsequently develops angio fibroblastic dysplasia.^[6]

It is more accurately described as a partially reversible but degenerative overuse tendinopathy.^[7] Elbow tenderness and pain with resisted wrist extension are common manifestations of lateral epicondylar tendinopathy. Patients with ongoing symptoms after non-operative treatment of lateral epicondylitis are usually treated with surgical release. Platelet-rich plasma injection is an alternative treatment option.

In the literature, there is a paucity of evidence regarding the etiology of this disease leading to the availability of multiple treatment options.^[8] Local injection therapy is the mainstay of treatment for lateral epicondylitis. Corticosteroid injections are most commonly used in clinical practice since the steroid mainly has anti-inflammatory effects. It has been suggested that the anti-inflammatory effect of corticosteroids is exerted by suppressing the granulomatous response in traumatized tissue and helps to alleviate pain. They also inhibit fibroblast and ground substance protein proliferation.^[9] Its role in preventing degeneration and long term curative effects are debatable.

Recently the role of biologics in management of lateral epicondylitis got attention mainly due to the fact that tendinosis is not an acute inflammatory condition but rather a failure of normal tendon repair.^[10] Platelet rich plasma is most commonly used biological in clinical practice and the main growth factors released from PRP TGF-beta 1, VEGF, PDGF, and CGF aid in the process of tissue repair, by promoting cellular growth and division, blood vessel formation, elimination of tissue debris, chemotaxis, and the creation of the extracellular matrix.^[11]

We conducted a randomized control trial to compare the efficacy of corticosteroid and PRP in pain reduction and functional outcome in lateral epicondylitis patients.

In our study we assessed the pain relief post injection by downgrading the Visual analogies scale (VAS) score and a reduction in the pain component of PRTEE score. We that patients in our study had severe pain pre procedure ranging from 5 to 7 with a mean of 6.3 in PRP group and 6 in the steroid group. Steroid group showed immediate relief in symptoms and decline in mean VAS scores from the first week post injection. PRP group showed gradual decline in symptoms with improved mean VAS score. This observation in our is similar to observation done by Peer booms et al,^[12] where they noted statistically significant sudden reduction in VAS score and DASH score in the corticosteroid group and gradual reduction of VAS score and DASH score in PRP

group. But the improved VAS score was insignificant between both groups producing similar results at final follow up.

The Patient-Rated Tennis Elbow Evaluation (PRTEE) Score is calculated to determine the functional disability in doing day-to-day activities in Lateral Epicondylitis patients. It is calculated using a standard questionnaire. It contains 2 components Pain component and Functional component. The final score is calculated by adding these 2 components.^[13]

In our study the pre-procedure score ranged from 53.1 to 64.7 in PRP group and 48 to 61.7 in corticosteroid group with mean of 58.7 and 54.7 in PRP and Steroid group respectively. PRP group showed gradual improvement in the functional score and in Steroid group functional score improved suddenly from the 1 st week post injection and at the end of 12th week mean value of functional score became 0.45. at 24 th week final follow up mean value increased to 3.5 due to recurrence of symptoms of lateral epicondylitis in 1 patient. But this observation was statistically insignificant and produced similar results between both groups at final follow up. Our results were also similar with that of Palacio et al study in which PRTEE and DASH scores were measured and found to have significant improvement at final follow up in both groups.^[14]

In our study we found that steroid injections had short-term improvement in symptoms, VAS, and PRTEE score this observation matches the results of other previous studies and metaanalysis.^[15] Short-time beneficial effects are mainly due to the anti-inflammatory effects of steroids and due to the short half-life of steroid injections long-term effects are less, once the patient becomes pain free patient resumes injurious activity without proper rehabilitation and before tendons gain full strength.^[16]

Adverse Reactions: In our study one patient in the steroid group who was symptom free for 12 weeks, developed recurrence of symptoms at 24 week follow up and a further patient lost follow up after 24 weeks. 3 patients in the steroid group developed hypopigmentation at the injection site at the 1st week of follow up. Hypopigmentation probably occurs due to reduction of number or activity of melanocytes by steroids and this hypopigmentation is temporary which settles down by itself at 6 weeks without any intervention.^[17] Similar findings were noted in a patient of Krogh TP et al.^[18]

2 patients of the PRP group had persistent severe pain after injection for 1 week which subsided by analgesics. The post-injection severe pain can be explained by the presence of physiological inflammatory mediators in PRP.

No patients in both groups had signs of infection during the study. This observation was similar to previous studies done by Krogh TP et al and Palacio EP et al.^[14,18]

CONCLUSION

Methyl prednisolone corticosteroid showed immediate effects in lateral Epicondylitis. Steroid injections showed faster improvement in terms of VAS, pain and Function scores compared to PRP. Both PRP and Methyl prednisolone showed similar results at final follow up. Steroid is more economical compared to PRP but had adverse reactions. Both PRP and Methyl prednisolone are beneficial in treatment for lateral epicondylitis. However, no drug was found to be superior over the other based on the outcomes at final follow up.

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