Original Research Article

A Comparative Study Of Intralesional PRP Injections Versus Conventional Steriod Injections In The Treatment Of Chronic Lateral Epicondylitis (Tennis Elbow)

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Abstract

Introduction: Tennis elbow or lateral epicondylitis (LE), is one of the most common and painful musculo-skeletal conditions, which has a significant impact on the healthcare industry and society. The disease mostly affects people aged between 35–50 years, who have a history of repetitive activities involving the upper limb. LE is more of a localised degenerative condition than an inflammatory one. The disease affects the normal healing potential of the tendon. Definitive management of chronic Lateral epicondylitis remains a challenge, considering its high rate of recurrence and episodes that can last from 6 months to 2 years. **Materials and Methods:** The Study was planned and conducted as a longitudinal observational study in Orthopaedics department, Pushpagiri Institute of Medical Sciences and Research Centre, Thiruvalla, from January 2018 to June 2019. Forty-four patients with chronic lateral epicondylitis refractory to NSAIDS and physical measures were included in the study, of which half of the patients consulted one orthopaedician who uses corticosteroid (methyl prednisolone) as a treatment for refractory Lateral Epicondylitis and the other 22, consulted an orthopaedician who uses PRP for the same. Diagnosis was made after clinical evaluation and after other causes for the symptoms ruled out. The primary analysis included Visual Analogue Scale (VAS) scores for pain and Mayo Elbow Scores for functional improvement. Patients were given injections on day 1 and then after 1 month and finally at two months. They were called in for follow up at 26 weeks and VAS and Mayo scorings were done. The values were compared with the initial values and statistically assessed for any significant variation.**Results**: Successful treatment was defined as more than 25% a reduction in VAS score OR more than 25 percent improvement in Mayo elbow scores. The results showed that, at the end of 26 weeks, a mean reduction in VAS score of 6.14 was achieved, among patients in the PRP group as compared to a reduction in VAS score of 5.5 at 26 weeks in steroid group. The improvement in VAS score was statistically significant (P = 0.02) for the patients in PRP group. Furthermore, according to the Mayo scores, of the 22 patients, all 22 patients showed improvement in function among patients in the PRP group. The PRP group of patients reported more reduction in pain than the Corticosteroid group of patients at the end of 26 weeks.**Conclusion:** PRP injection relieves pain significantly and also improves function, exceeding the effect of corticosteroid injections at 26 weeks. Future decisions for application of PRP for lateral epicondylitis should be confirmed by further long-term follow-up and should take into account possible costs and harmful effects as well as benefits.

Keywords: lateral epicondylitis; platelet rich plasma; corticosteroids.

Introduction

Tennis elbow or lateral epicondylitis (LE), is one of the most common and painful musculo-skeletal conditions, which has a significant impact on the healthcare industry and society[1,2].It was first described by Runge in 1873(as documented by R.S Graham, a British surgeon in 1961). It was initially referred to as "Lawn Tennis arm", by Henry Morris, in 1882 in the *Lancet*[3]. It was described as a chronic symptomatic degeneration of the wrist extensor tendons involving their attachment to the lateral epicondyle of the humerus. Lateral epicondylitis is a common term used to describe a group of symptoms including pain and tenderness over the origin of extensor muscles of the wrist and fingers[4,5],having a prevalence rate of more than 1% among the general population, and with a slight predominance among females.The disease mostly affects people aged between 35–50 years, who have a history of repetitive activities involving the upper limb[8,9]. While the exact pathophysiology behind the condition is not yet clear, and despite the presence of inflammatory cells locally, there is a strong argument that Tennis Elbow can be regarded as a degenerative process caused by muscle overuse, with subsequent tendinosis, micro-trauma and tear of the extensor carpi radialis brevis tendon (ECRB). The condition mostly occurs in patients whose activities require strong gripping or repetitive wrist movements[6].

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Aims and Objectives

1. To compare the long-term effects of corticosteroid injections and PRP injections in the treatment of chronic lateral epicondylitis.
2. To study the potential of a regenerative treatment modality like PRP in the treatment of chronic LE.
3. To re-affirm PRP as a promising treatment in Lateral Epicondylitis.
4. To study adverse effects of corticosteroid injections in Tennis Elbow.

Materials and Methods

Hypothesis: The hypothesis of the study is PRP injections provide more significant pain relief and improvement in functional outcome

than Steroid injections in the long-term treatment of Lateral Epicondylitis.

Study Design: Comparative Study

Study Population: Patients with symptoms and signs suggestive of Lateral Epicondylitis of more than three months duration not subsiding with rest or analgesics will form the cases and age matched subjects will form the controls.

Study Setting: Department of Orthopedics, Pushpagiri Institute of Medical Sciences and Research Centre, Tiruvalla-689101, which is a 1200 bedded tertiary care medical college hospital in South Kerala.

Study Period: The duration of study is 1.5years (January 2018-June 2019)

Sample Size: Assuming the mean and SD of PRP injections and steroid injections from previous study, α was taken as 5% and power of study as 80%, Type 1 error as 5 %, sample size was calculated using the formula

$n=S12+S22[Z1-2+ Z1-\beta]2x1-x2 = 18$

Counting for 20% lost follow up, corrected sample size= 18+3.6 = 21.6 Approximately 22.

Sampling Methods: Allotment of the treatment modality was decided by the consultant after obtaining consent from the patients for this study and Cases and Controls were chosen Consecutively from the same.

Inclusion Criteria

PRP group

Age Group: 30-60 years.

Symptoms and signs suggestive of unilateral or bilateral Tennis Elbow (unresponsive to treatment with NSAIDS and immobilization) of more than 3 months duration.

Steroid group

Age Group: Age matched with cases, with similar symptoms.

Exclusion Criteria

- Patients with trauma to the affected elbow.
- Patients who underwent surgeries in the affected elbow.
- Patients with degenerative elbow joint diseases.
- Patients with tumours in the affected elbow.
- Patients who have undergone the treatments included in the study.

Ethics: Study was formulated after obtaining approval from Institutional Research and Ethical Committee. Informed consent will be secured from patients satisfying the criteria. Data safety norms will be followed to preserve confidentiality and privacy of the patient.

Budget: All expenses were borne by the researcher.

Equipment: The portable centrifuge used in this study is REMI-R8C plus.

Patient Preparation: Informed consent was obtained from all patients before they were enrolled in our study. Patients were asked not to take any medication for the ailment being studied two weeks prior to the injections. They were asked to continue their routine activities.

Study Tools

1. Proforma
2. X-ray Anterio Posterior and Lateral views of affected Elbow
3. 40 mg Depomedrol (Methyl prednisolone) for each of the patients in steroid group.
4. Platelet Rich Plasma (prepared from each patient's own blood).
5. Sodium citrate
6. Visual Analogue Scale
7. Modified Mayo questionnaire

Study Procedure

All patients coming to Pushpagiri Institute of Medical Sciences and Research Centre, Thiruvalla with symptoms and signs suggestive of Lateral epicondylitis (Tennis elbow) of more than 3 months duration and failed conservative management (immobilization and analgesics) initially underwent X ray of the affected elbow to rule out other diagnoses. Mill's test and Cozens test performed to confirm the diagnosis of Tennis Elbow.

After ruling out other causes, patients were asked to abstain from taking analgesics or resting for a period of two weeks. They were called back at the end of two weeks for the procedure.

Patients consulting one particular consultant were given an injection of 2.5 ml of platelet rich plasma and age matched patients consulting another consultant were given an injection of 40mg Depomedrol (Methyl prednisolone) following all aseptic precautions. Patients were asked strictly not to take any analgesics (oral or injections) throughout the course of the study. The same injections were repeated after 4 weeks and 8 weeks respectively. In case of patients with bilateral affection, similar injections were administered to both elbows but only the worse elbow was included in the study. Patients of both groups underwent assessment of pain and functional outcome, based on Visual Analog scale of pain and Mayo scoring after 26 weeks (period of maximum effect of both interventions based on previous studies). Results of the patients with PRP injections was compared with that of the patients who received steroid injections.

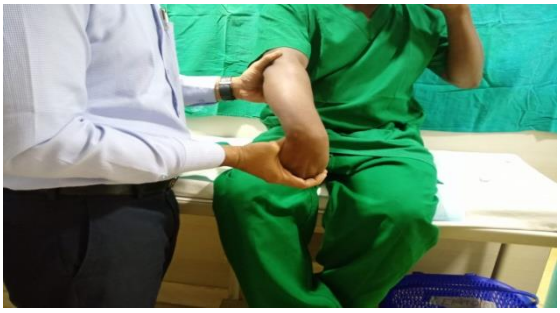

Fig 1:Performing Mill's Test

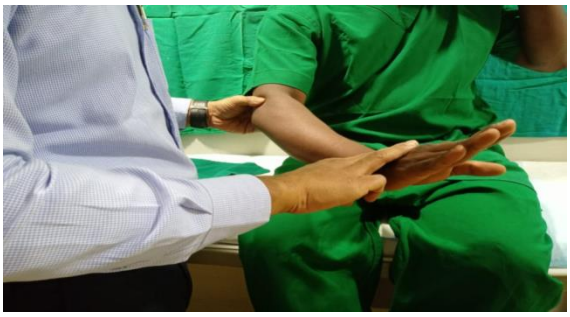

Fig 2: Performing Cozens test

Fig 3: Performing Maudsley's Test

Procedure

For patients in the STEROID group, an injection of 40mg of Depomedrol (Methyl prednisolone) was injected under strict aseptic precautions in the theater. The region of maximum tenderness on palpation was chosen as the site for injection. For patients in the PRP group, 2.5 ml of platelet rich plasma prepared from the individual patient's own blood just prior to the injection, was injected to the affected area. The site for injection was decided in the same manner as for steroid.PRP was prepared and administered. in the theatre following all norms of asepsis. 14.5 ml of venous blood was collected from each patient via venipuncture from the unaffected or less affected arm. The blood mixed with 0.5 ml of autoclaved sodium citrate (anti-coagulant) and the mixture centrifuged at 1500 rotations per minute for 15 min. (soft spin). The plasma layer obtained from the first centrifuge was separated through careful pipetting and the isolate centrifuged further at 2500 rotations per minute for 15 min (hard spin). Following this, PRP was pipettes out from the lower one third of the test tube, and transferred to syringes for injection. No exogenous factors were used for activation of PRP. The injections were administered in a minor theatre undermost utmost sterile precaution. Both injection sites were dressed with gauze dressing after the procedure. The tubes and pipettes once used, were discarded.Patients were asked to abstain from any form of activity of the affected limb for 2 days after each procedure. They were asked not to take any pain medication during the entire course of the study. The injections were repeated at 4 weeks and 8 weeks and patients called in for re-evaluation at 26 weeks.

Fig 4: Remi R-8C Plus Centrifuge used in the study

Fig 5: The Frozen cell glass tube used for PRP preparation

Fig 6: After soft spin, plasma separated from erythrocytes. The black arrow on top shows the plasma layer and the white arrow at the bottom shows the erythrocyte layer

Fig 7: After hard spin the lower one third (denoted by white arrow) becomes the platelet rich layer, and the top two thirds the platelet poor plasma layer

Fig 8: PRP mixed with Local Anesthetic prior to injection

Fig 9: Injecting the Mixture of PRP and Local anesthetic

Outcome Variables

Pain Intensity

VAS

Pain severity were evaluated before injection and re-evaluation done at 26 weeks. Visual analogue pain scale (VAS) (range, 0 [no pain] to 10 [agonizing pain]). The validity and reliability of self-rating scales like the VAS have previously been described in other studies.

Functional Outcome

Modified Mayo clinic performance index

"Modified Mayo Clinic performance index" for the elbow will be used as a valid and reliable measure to evaluate the functional improvement after therapy. The Mayo Clinic performance index for the elbow has 4 parameters: Pain, motion, stability and daily function. The maximum score is 100 and the minimum index is 0, the results are interpreted as excellent (> = 90), good (75-89), fair (60-74) and poor (<60). The pain parameter carries the highest points. Mayo questionnaire was filled out by interviewing each patient initially and on follow up evaluation.

Method Of Data Entry And Statistical Analysis

Data will be entered using Microsoft excel and analyzed using SPSS 2.0 Frequency and percentages will be found out for all categorical variables and mean (SD) will be calculated for continuous variables. Success rate is defined as greater than 25 percent reduction in VAS score when compared to baseline. P-value of <0.05 will be taken as statistically significant.

Results

Demographic variables

Mean age of the subjects participated in the study were among STEROID group was37 ± 4.5 years and among PRP group was 39.4 ± 6.2 (Table and Figure:). Of the 44 cases,63% were females and 36% were males among STEROID group and in the PRP group, 45% were males and 55% were females (Table. 7 and Figure: 21(B)). Of the 44 cases 57% of subjects were housewives.

Table 1: Age distribution among STEROID and PRP groups

Age	STEROID		PRP	
	Count	Percent	Count	Percent
21-30	2	9	0	0
31-40	14	64	16	73
41-50	6	27	4	18
51-60	0	0	0	0

Majority of the patients were in the age group of 31-40 (68%)

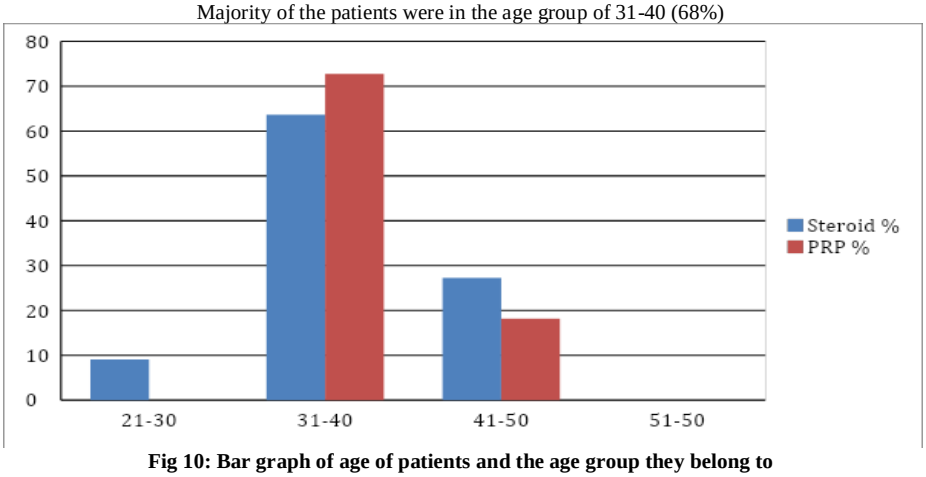

Fig 10: Bar graph of age of patients and the age group they belong to

Table 2: Distribution of gender between STEROID and PRP groups

Gender	STEROID		PRP	
	Count	Percent	Count	Percent
Male	8	36.4	10	45.5
Female	14	63.6	12	54.5

Majority of the patients were females- 26 (59%)

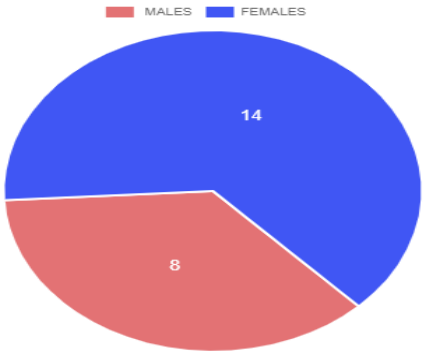

Fig 11: Pictorial representation of gender among patients in each group

Table 3: Distribution of Occupation of Steroid group and PRP group

Occupation	Steroid Test Participants n = 22		PRP Test Participants n = 22	
	Count	Percent	Count	Percent
Housewives	13	59%	12	55%
Machine Operators (Automobile Drivers)	5	23%	4	18%
Sports Personnel	0	0%	2	9%
Medical Personnel (Doctors, Nurse etc.)	4	18%	4	18%
Others	0	0%	0	0%

Majority of the patients were housewives- 25 (58.8%).

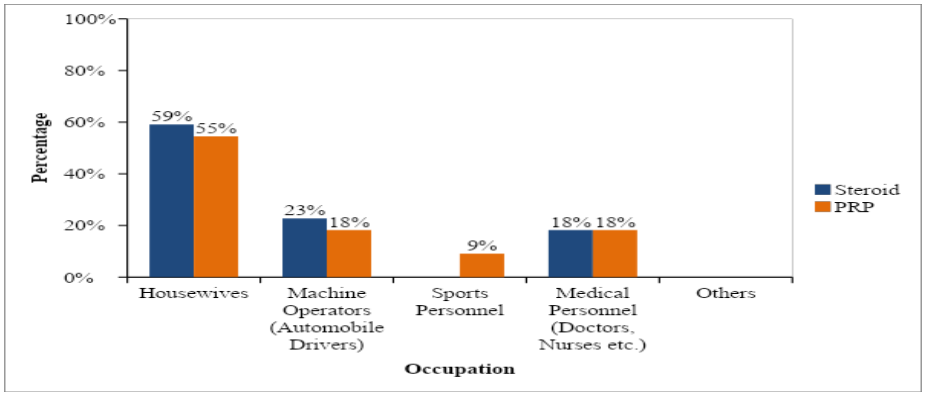

Fig 12: Distribution of occupation among cases and controls

Symptomatology

Mean duration of symptoms for the affected were 7 ± 3.01 months (Table and figure 2). Of the 44 cases studied 58% had unilateral symptoms and 42% had bilateral symptoms (Table 5 and figure 25).

Table 4: Percentage distribution of duration of symptoms

Total Test Participants n = 44		
Duration of Symptoms (in months)	Count	Percent
3	1	2%
4-6	20	46%
7-9	16	36%
10-12	5	11%
More than 13	2	5%

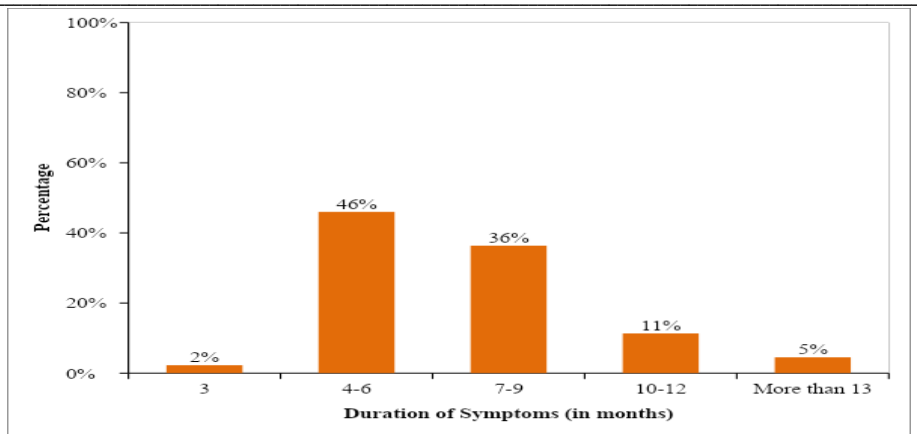

Fig 13: Bar diagram showing duration of symptoms

Table 5: Side of affection

36 out of 44 patients had unilateral symptoms.

Symptoms	Count	Percent
Unilateral	36	58.0
Bilateral	8	42.0

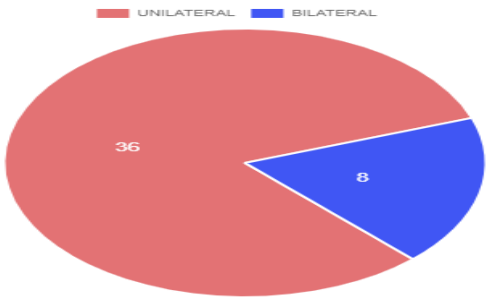

Fig 14: Pie chart showing side of affection

Table 6: Symptoms with respect to side of affection

Symptoms	STEROID	PRP	Total	Percentage
Dominant	17	18	35	80.0
Bilateral	4	4	8	18.0
Non dominant	1	0	1	2.0

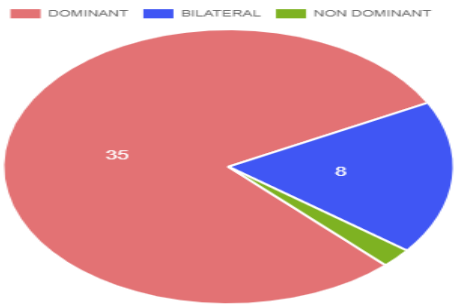

Fig 15: Pie chart showing dexterity of symptoms

Clinical Tests

64 % of cases had a positive COZENS's AND MILL's test. 27% had only COZEN's test and 9% had only MILL's test positive.

Table 7: Clinical Tests

Clinical Test	Cozen's Only	Mills Only	Both
No. of Patient	12	4	28
Percentage	27%	9%	64%

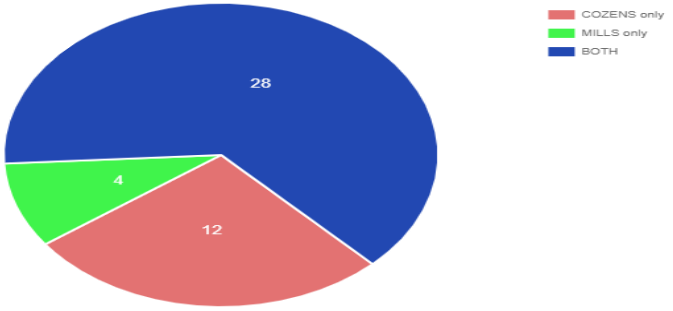

Fig 16: Comparison of clinical tests among patients

VAS Scores

Visual analog scale (enclosed in annexure) was used to quantify pain prior to the injections and at 26 weeks for each patient.

Table 8: VAS scores prior to injections

VAS Score Before Injection (0-10)	STEROID		PRP	
	Count	Percent	Count	Percent
0 (no pain)	0	0%	0	0%
1-3 (mild pain)	0	0%	0	0%
4-5 (moderate pain)	0	0%	0	0%
6-7 (severe pain)	8	36%	9	41%
8-9 (very severe pain)	14	64%	12	54.5%
10 (excruciating pain)	0	0%	1	4.5%

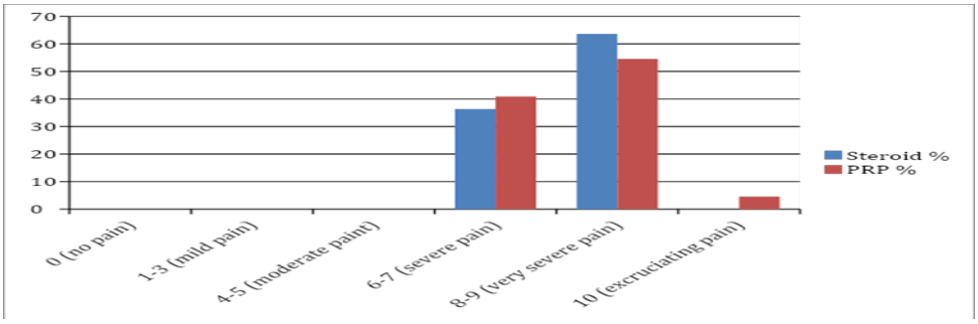

Fig 17: Bar graph denoting VAS score in each group

Table 9: VAS scores at 26 weeks after injection

VAS Score at 26 Weeks (0-10) After Injection	STEROID		PRP	
	Count	Percent	Count	Percent
0	3	14%	5	23%
1-3	13	59%	14	64%
4-5	5	23%	1	4%
6-7	1	4%	2	9%
8-9	0	0%	0	0%
10	0	0%	0	0%

Table 10: Mayo scores initially

Mayo Elbow Scores Initial	STEROID		PRP	
	Count	Percent	Count	Percent
>90	0	0%	0	0%
75-89	3	14%	6	27%
60-74	12	54%	11	50%
<60	7	32%	5	23%

Table 11: Mayo scores at 26 weeks

Mayo Elbow Scores 26 Weeks After Injections	STEROID		PRP	
	Count	Percent	Count	Percent
>90	10	46%	16	73%
75-89	8	36%	3	14%
60-74	4	18%	2	9%
<60	0	0%	1	4%

Table 12: Reduction in Vas score and improvement in Mayo scores-mean median and SD

Group			Reduction in the VAS Score	Improvement in Mayo Score
STEROID	N	Valid	22	22
		Missing	0	0
	Mean		5.27	22.73
	Median		5.50	23.00
	Std. Deviation		1.202	7.079
PRP	N	Valid	22	22
		Missing	0	0
	Mean		6.14	21.73
	Median		7.00	22.00
	Std. Deviation (SD)		1.983	10.955

Mann-Whitney Test

Table 13:P value calculation for each scores

	Reduction in the VAS Score	Improvement in Mayo Score
Mann-Whitney U	145.500	231.500
P value	.021	.805

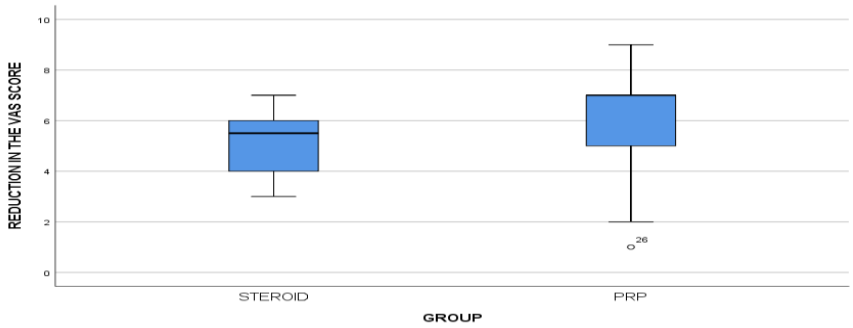

Fig 18: Reduction in VAS scores, pictorial representation

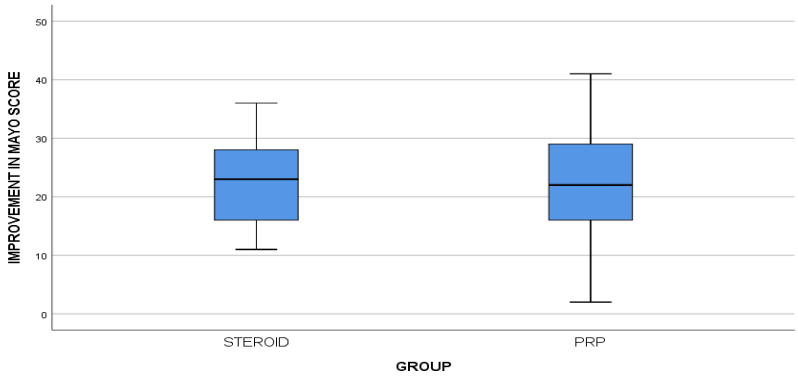

Fig 19: Improvement in Mayo scores, pictorial representation

At 26 weeks, all 22 patients of the Steroid group showed improved VAS and Mayo scores, and 20 patients in the PRP group showed improvement in both scores. 3 patients from Steroid group and 5 patients from PRP group were found to have complete relief from pain (VAS score of 0). No patients in either group complained of pain lasting more than 24 hours following the injections. There were no post procedural localized infection or signs of it throughout the study. Two patients in the steroid group developed hypopigmented patches at the site of injection at 26 weeks follow up. For the Steroid group mean VAS score was 7.68 ± 0.945 initially and at 26 weeks was 2.41 ± 1.652. For PRP group it was 7.86 ± 1.082 initially and 1.73 ± 1.932 at 26 weeks. Mean reduction in VAS score was 5.27 ±

1.2 and improvement in Mayo score was 22.73 ± 7.07 for Steroid group and 6.14 ± 1.98 and 21.73 ± 10.955 for PRP group respectively. With respect to reduction in VAS score for both groups p value was found to be 0.02 and hence significantly more for PRP group when compared to steroid group.

Discussion

Definitive management of chronic Lateral epicondylitis remains a challenge. Local corticosteroids are used to reduce inflammation in patients with chronic tendinopathies. However, inflammation is not a major feature in many of these lesions and, if present, is a vital component of the healing response. Inhibiting this process may result in a suboptimal outcome. Corticosteroid injections were once considered as the gold standard in the treatment of lateral epicondylitis. Presently their use as a definitive treatment for LE is debatable, as it is a proven fact that steroids suppress inflammatory response locally and systemically. Thus they may retard the healing process within the tendon. Efficiency of Platelet Rich Plasma for treating tendinopathies has been vastly studied and the results obtained have been mostly positive[7].In our study which was conducted from January 2018 to June 2019, 44 patients with chronic refractory Lateral Epicondylitis, took part. Patients in each group consulted two different orthopaedicians for lateral epicondylitis of more than 3 months duration which was refractory to NSAIDS and physiotherapy [8]. Other causes of chronic elbow pain were ruled out. Patients who took similar treatments for the same ailment in the past, as well as patients with systemic diseases were excluded from the study. Majority of the patients were housewives and were affected unilaterally in the dominant side. Mean age group was 31-40 and mean duration of affection was 7 months. One group of 22 patients consulting one orthopedician was administered 40 mg of methyl prednisolone (commercially available as Depomedrol) and Platelet Rich Plasma (PRP) prepared from patients own blood was administered to the other group. No exogenous factors were used for activation of PRP[9].Both injections were administered under strict aseptic precautions. Injections were administered on day 1, after 1 month and after 2 months respectively, and patients called in for follow up and assessment at 26 weeks post first injection. VAS and Mayo elbow scoring were done initially and at 26 weeks to assess the progress in patients[10].At 26 weeks follow up patients in the PRP group were found to significantly more reduction in pain than those in the Steroid group. Patients in both groups reported improvement in function of the affected elbow. 2 patients from corticosteroid group developed hypopigmented patches at the injection site. There were no incidents of infection or allergic reactions to either injections at the end of the study.

Conclusion

Hence in our study PRP has shown to provide significantly more symptomatic improvement than corticosteroids in the treatment of chronic tennis elbow. This could probably be attributed to the healing potential of PRP owing to the numerous growth factors present in it.Hence it may be considered as a viable treatment option for Chronic Lateral Epicondylitis, as the underlying pathology is most probably corrected, unlike steroid injections. Further studies as well as long term follow ups are required to assess and estimate the therapeutic efficacy of PRP as well as its potential in inducing microvascular healing in tendinopathies like Tennis Elbow.

Limitations of the Study

1. Longest follow up done for a patient in our study was 6 months. Thus, our results are mostly based on the short and intermediate term outcomes of each treatment modality (12-26 weeks). Hence it is recommended to have long term follow ups to find out recurrence rates in both groups.
2. We have compared the treatment outcome of PRP and corticosteroids in cohorts of 22 patients each, which is a major limitation. Hence the study is being planned to be continued to include a larger cohort.

Conflict of Interest: Nil
Source of support:Nil

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