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To assess the functional outcome of platelet rich plasma vs conservative treatment (bracing) in Tennis elbow patients

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Abstract
Introduction: Lateral elbow pain (tennis elbow) is one of the most frequently diagnosed musculoskeletal disorders in the upper extremity in a primary care setting. It has an incidence of 4-7 per 1000 per year in general practice, with a peak between the age groups of 35-54 years, with a mean age of approximately 42 years. Over-use from many activities has been reported to be the cause of lateral elbow pain. The patient usually presents with pain over the elbow region and on examination, tenderness over the lateral epicondyle is present. The aim of the study was to compare the functional outcome of PRP and Bracing in patients with tennis elbow.
Methods and materials: 68 Patients diagnosed as Tennis elbow and treated at our institute between March 2017 to February 2018 and those who were followed up in Out Patient Department upto June 2018 were retrospectively studied. Patients with polyarthritis, arthritis of the Elbow, previous fracture of the elbow and patients with neurological condition were excluded. 68 patients diagnosed with chronic lateral epicondylosis were randomly divided into two groups. Group A with 2 ml of PRP mixed with 1 ml of 2% xylocaine and Group B with Bracing and conservative treatment(NSAIDS and ice fomentation, physiotherapy). Pain and functional improvements were assessed using visual analogue scale (VAS) and mayo scoring at 0, 1, 2, 4, 12 and 24 weeks.
Results: Among 68 patients with tennis elbow (39 males and 29 females) post-PRP injection and Conservative treatment (Bracing, NSAIDS) significant differences were observed between VAS and Mayo elbow performance score score at baseline and after 1wk, 2wk, 4wk, 12wk and 24wk ($P<0.007$).At the end of first week of treatment recovery or improvement was reported in 86.11% patients (31) in the PRP group and 53.13% in the brace group.
Conclusions: Our results demonstrated good functional outcome with patient treated with PRP with 2% xylocaine and it sustained over longer period of time. Intially as well as later on results in patients treated with PRP with 2% xylocaine was better in comparision with conservative treatment (Bracing, NSAIDS and ice fomentation). It is safe and a significant improvement has been observed in VAS score and Mayo elbow performance score for tennis elbow. On long term follow-up, PRP seems to be the more effective treatment with more persistent efficacy than conservative treatment (Bracing and NSAIDS) in relieving the pain.

Keywords: tennis elbow, PRP injection, Mayo elbow performance score, brace

Introduction

Lateral epicondylosis (tennis elbow) is one of the most frequently diagnosed musculoskeletal disorders in the upper extremity in a primary care setting. It has an incidence of 4-7 per 1000 per year in general practice, with a peak between the age groups of 35-54 years, with a mean age of approximately 42 years [1-3]. The condition is more common (affecting 15%) in individuals involved in repeated forceful twisting, gripping, lifting heavy weights, throwing, pulling activities or combination of these activities and in those using vibrating tools [4, 5, 6].

Various methods have been advocated for the treatment of Tennis elbow. They include rest, nonsteroidal anti-inflammatory medication, bracing, local ultrasound, Local injection of corticosteroids, Local injection of platelet rich plasma and low-level laser therapy. Various types of surgical procedures have also been recommended but they are required Very rarely in resistant and recurrent cases. Treatment modalities like Local injection of platelet rich plasma and low-level laser therapy have shown good results but are not available at all centres [7, 8, 9, 10]. Since Tennis Elbow is quite common condition all patients cannot be referredto higher centres for treatment [11, 12].

Recently, platelet rich plasma (PRP) has been promoted as an ideal biologic autologous blood derived product. PRP is defined as volume of the plasma fraction of autologous blood having a platelet concentration above baseline [13, 14, 15]. It can be exogenously applied to various tissues where, upon platelet activation, a release of high concentrations of platelet derived growth factors occurs [16, 17]. These growth factors trigger stem cell recruitment, increase local vascularity and directly stimulate the production of collagen by tendon sheath fibroblasts. Platelet rich plasma applications enhance wound healing, bone healing and also tendon healing.

Materials and methods

Patients diagnosed as Tennis elbow and treated at our institute between March 2017 to February 2018 and those who were followed up in Out Patient Department upto June 2018 were retrospectively studied. 68 patients diagnosed with chronic lateral epicondylosiswere randomly divided into two groups. Group APRP with 2% xylocaine and Group B Brace group.

Inclusion criteria

All patients with a new episode of Tennis elbow (pain and tenderness over lateral region of the elbow and no history of similar complaints in past) were included in the study.

Exclusion criteria

Patients with polyarthritis, arthritis of the Elbow, previous fracture of the elbow and patients with neurological condition were excluded.

The study was approved by the research ethics committees and informed written consent was obtained from all patients. We could trace records of 68 patients who fulfilled our inclusion, exclusion and follow up criteria. Of these patients westudied, 36 patients were treated with Local Injection of PRP with 2% xylocaine, 32 patients were treated with Brace.

Group A: PRP with 2% xylocaine: These Patients were infiltrated with 2 milliliters of freshly prepared PRP mixed with 1 milliliter of 2% xylocaineat the lateral epicondyle by the technique mentioned below.

Group B: Brace group: These patients were treated with application of Tennis Elbow Brace which is available everywhere. Patients were advised to apply Brace over upper third of forearm for 6 weeks. In addition all these patients received 15 minutes of Ice fomentation for 2 days and 5 days course of oral NSAIDS and physical therapy by physiotherapist in the form of passive exercises initially followed by judicious active and resisted exercises.

PRP preparation

The patient was placed in a comfortable and appropriate position that allows for sterile access to the site of injection. At first, 20 ml of blood was collected from the patient's contralateral upper extremity cubitalvein under aseptic conditions into four vacutainers containing anticoagulant. These four vacutainers were subjected to a first spin in a centrifuge at a speed of 2500 RPM for 10 minutes. After the first spin 3 layers appeared. The deep layer consists of red blood cells, the middle layer contains platelets and leukocytes, and the top layer is made up of platelet-poor plasma. The top and middle layers were transferred to a fresh vacutainer. The plasma was then subjected to a second spin at a speed of 3500 RPM for 15 minutes. The plasma at the bottom, which is rich in platelets was separated and used for infiltration.

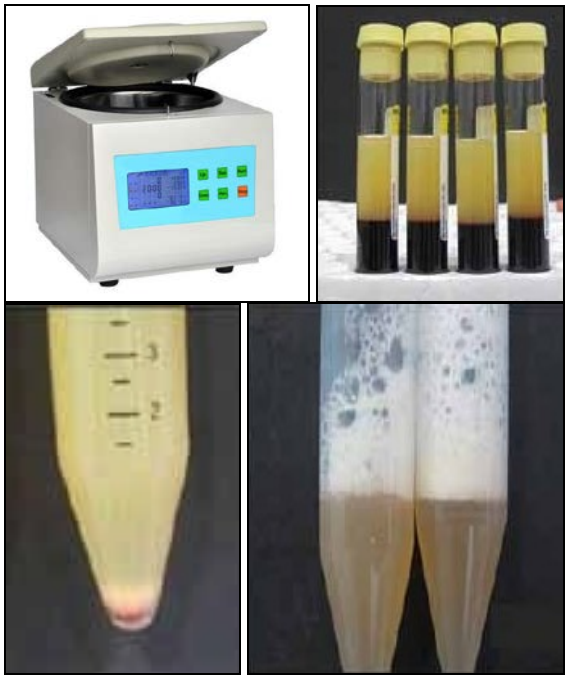

Fig 1

Injection technique

The elbow is flexed to 90° with forearm in pronation. The injection site is painted and draped. Radial head is palpated while pronating and supinating the forearm. The needle (22 G) is introduced proximal to the radial head on lateral epicondyle at the point of maximum tenderness and in the vicinity (around the tendon of ECRB). Multiple pricks were made in the tendon (peppering technique) and contents of syringe were injected slowly. Patients were advised to give rest to the upper limb, avoid heavy activities for three days, after which no restriction on activity was advised.

Fig 2

All Patients were followed as per routine protocol and at each follow up visit functional assessment was done as per Mayo's +elbow performance score mentioned below:

Section 1: Pain Intensity
1. None: 45 pts
2. Mild: 30 pts
3. Moderate: 15 pts
4. Severe: 0 pts

Section 2: Motion Arc of motion
1. greater than 100 degrees- 20 pts
2. Arc of motion between 50 and 100 degrees 15 pts
3. Arc of motion less than 50 degrees 5 pts

Section 3: Stability
1. Stable: 10 pts
2. Moderate instability: 5 pts
3. Grossly Unstable: 0 pts

Section 4: Function
1. Can comb hair: 5 points
2. Can eat: 5 points
3. Can perform hygiene: 5 points
4. Can don shirt: 5 points
5. Can don shoe: 5 points

Interpreting the Mayo Elbow Performance Score
Score greater than 90 Excellent
Score 75-89 Good
Score 60-74 Fair Score
Below 60 Poor
All the above points were aggregated and outcome measured on 0-100 point scale. Score greater than 90 Excellent, score 75-89 Good, score 60-74 Fair, score below 60 Poor.

Sample size
Study observed mean values of VAS in PRP group at 12 weeks was 4.1± 1.25 at 26 weeks was 3.84 ± 1.46. Taking these values as reference and assuming mean difference of PRP with brace group as 1.2, the minimum required sample size with 90% power of study and 5% level of significance is 32 patients in each study group. So minimum sample size should be 64 with 32 each group. Comparison between Platelet Rich Plasma (PP) and Xylocaine infiltration for lateral epicondylosis (Tennis Elbow) was observed by Vishnu Vardhan Reddy, *et al*.
Formula used is:-
For comparing mean of two groups

$$N>=2\ \frac{(\text{standard deviation})^2}{(\text{mean difference})^2}*(Z_\alpha + Z_\beta)^2$$

Where Z_α is value of Z at two sided alpha error of 5% and Z_β is value of Z at power of 90% and mean difference is difference in post intervention mean values of two groups.

Calculations
1. VAS at 12th week
$N>= (2*1.25*1.25*(1.96+1.28)^2)/(1.2)^2= 22.78=23$(approx.)
2. VAS at 26th week

Analyses were carried out with SPSS version 25.

Results
68 patients were retrospectively evaluated of which 36 patients received local injection of PRP with 2% xylocaine and 32 patients received treatment with Brace.
In the above two groups patients characteristics were comparable

Table 1: Baseline characteristics of the study sample

Patient Types	Group A Local injection PRP with 2% xylocaine	Group B Brace group	Total
Total no. of patients	36	32	68
Males	21	18	39
Females	15	14	29
Average Age	41.8 years	38.6 years	40.3 years
Sedentary Work	3	1	4
Moderate Work	8	9	17
Heavy Duty Work	25	22	47

At one week outcome in the PRP group was significantly better than in the brace group (Graph 1). At the end of first week of treatment recovery or improvement was reported in 34 patients (95%) in the PRP group and 21 patients (65%) in the brace group. At second weekof treatment recovery or improvement was reported in 32 patients (90%) in the PRP group and 19 patients (60%) in the brace group.At fourth weekof treatment recovery or improvement was reported in 30 patients (85%) in the PRP group and 17 patients (55%) in the brace group. At the end of 4 weeks 3paitents in the PRP group complaint of recurrence of pain and 2 patients complaint of moderate pain during work. Pain relief and average functional outcome of Local injection of PRP Group was better as compared to Brace group at 4 weeks follow up examination and thereafter till end point of the study.

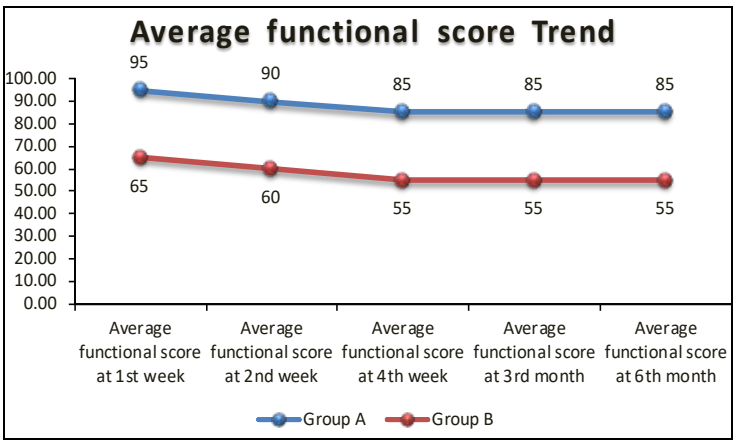

Fig 3

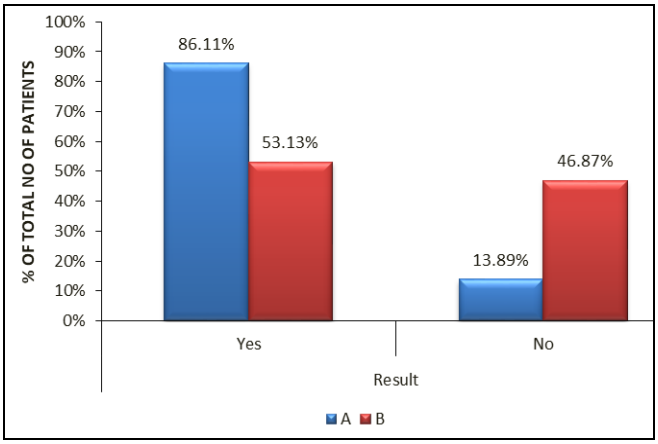

Fig 4

Table 2: Functional Assesment Scoring by Mayos Elbow Performance score for the treatment of Group A and B.

Treatment Groups	Average functional score at 1st week	Average functional score at 2nd week	Average functional score at 4th week	Average functional score at 3rd month	Average functional score at 6th month
Group A Local injection of PRP with 2% Xylocaine	95	90	85	85	85
Group B Brace group	65	60	55	55	55

Table 3

		Group		Total	P value
		A	B		
Result	Yes	31 (86.11%)	17 (53.13%)	47 (69.12%)	0.007
	No	5 (13.89%)	15 (46.87%)	21 (30.88%)	
Total		36 (100%)	32 (100%)	68 (100%)	
		Group A	Group B		
Average functional score at 1st week		95	65		
Average functional score at 2nd week		90	60		
Average functional score at 4th week		85	55		
Average functional score at 3rd month		85	55		
Average functional score at 6th month		85	55		

Complications such as local skin infection was observed in one patient at 6 month and increase in severity of pain immediately after injection was seen in 2 patients which subsided completely in next 3 days. No complication were noted in patients treated in brace group.

Discussion

The current study strongly suggests that local injection of PRP is a novel form of treatment that provides significant relief of pain and improvement in function in both tennis elbow and plantar fasciitis. Moreover, it is possibly a safer option for patients than steroid use and surgery. The proposed mechanism of action of autologous PRP is improvement of early neotendonproperties [18] and improvement of tissue healing by enhancing cellular chemotaxis, proliferation and differentiation, removal of tissue debris, angiogenesis and laying of extracellular matrix [19]. Numerous methods such as rest, non-steroidal antiinflammatory medication, bracing, local ultrasound andInjection of corticosteroids have been advocated for treating Tennis Elbow patients with variable success rates [20]. Now a day's Local injection of PRP (platelet rich plasma) is considered as most successful treatment modality for Tennis Elbow patients. PRP releases growth factors and cytokines. These bioactive proteins stimulate the healing process in stress injury at origin of extensor tendons [21, 22]. But this form of therapy requires advanced equipment which is not available everywhere.

Clinical results in our study shown excellent results in those patients treated with Local injection of PRP with 2% xylocaineover those treated with Brace at follow up during 1st week, 2nd week 4th week 12th week and 24th week. In addition we found low recurrence rate with local PRP injection as compared with those patients treated with the use of Braces. 5% and 15% of patients in PRP Injection Group and Brace Group respectively required an average of 2 to 3 additional courses of oral Non-steroidal Antiinflammatory drugs and 2 courses of topical analgesics. Mild complications such as local skin infectionat the lateral epicondyle and Increase in severity of pain immediately after injection were seen in 4.4% of patients treated with local injection of PRP. Whereas no complications occurred in patients treated with Brace. Therefore overall functional outcome was better in patients treated with Local PRP injection therapy than in those treated with Tennis Elbow Brace.

Conclusions

Our results demonstrated good Functional outcome (Mayo's Elbow Performance Score) in patients treated with Local PRP therapy and it was sustained over long period of time with less number of additional treatments, less recurrences and no complications as against those treated with conservative therapy (Tennis Elbow Brace).

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