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Original Article

Comparison between Effects of Intralesional Platelet Rich Plasma and Corticosteroid Injection on Pain and Functional Outcome in Patients with Lateral Epicondylitis of Elbow

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Abstract

Background: A debilitating and painful elbow problem is lateral epicondylitis. **Objective:** In this study, pain and functional outcomes were examined in relation to intralesional platelet-rich plasma (PRP) and corticosteroid injections patients with lateral epicondylitis. **Methodology:** This randomized experimental study was done in the Department of Physical Medicine and Rehabilitation, Bangabandhu Sheikh Mujib Medical University (BSMMU) from March 2017 to February 2018. Thirty patients with diagnosed lateral epicondylitis, aged between 21- 60 years and had been ill for more than a month were enrolled and randomly assigned into two groups. In Group A received two doses of intralesional PRP injection, and Group B received two doses of intralesional corticosteroid injection. Pain and functional outcomes were evaluated by using a visual analog scale (VAS) for pain and a patient-rated tennis elbow assessment (PRTEE) questionnaire, respectively. In the lateral epicondylar region, intralesional PRP or corticosteroids were administered during the first (week 1=W1) and fourth (week 7=W7) treatment visits. **Results:** The findings revealed a statistically significant decline in pain over time, as well as improvements of functional outcomes in both groups as evidenced by significantly lower VAS scores and lower PRTEE scores up to 11 weeks post-injection. There was no discernible difference in progress between the two groups up until W1 to W9 scores, however at the eleventh week, group A showed greater improvement than group B ($p<00.5$). **Conclusions:** Intralesional PRP injection is a promising therapy option for lateral epicondylitis, offering sustained pain relief and improved functional outcomes over time compared to corticosteroid injection.

Key Words: Lateral epicondylitis of elbow; intralesional platelet rich plasma; corticosteroids; pain; functional outcome

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Introduction

Lateral epicondylitis (LE) is a painful, disabling, soft tissue injuries which affects Extensor Carpe Radialis Brevis (ECRB) due to high demand of gripping or repetitive wrist movements.[1,2] There are chronic degenerative changes that occur in the LE, which is the hallmarks of tendinosis.[1] The most typical signs of LE are lateral elbow discomfort, pain with wrist extension, and reduced grip strength[2] and it significantly lowers quality of life in daily activities.[3,4]

There are various conservative treatment modalities, which include pain medications, physical therapy such as ultrasound therapy, extracorporeal shock wave therapy, low-level laser therapy, therapeutic exercises and epicondylar counterforce orthoses. Interventions such as intralesional corticosteroid (CS) injection, autologous blood, platelet rich plasma (PRP) have shown promising effects.[1,4] Skin atrophy, skin depigmentation and fatty atrophy are noted after intralesional corticosteroid injections1. The transforming growth factor beta, epidermal growth factor, platelet-derived growth factor, and vascular endothelial growth factor all have a significant impact on tissue repair.[5] PRP may be more effective in promoting tissue repair due to its supra-physiological levels of growth factors.[5,6]

A randomized controlled trail, demonstrated that inadequate reduction of pain and disability in tennis elbow by the interventions with PRP and CS.[7] In a meta-analysis, comparison to intralesional CS injections with PRP in lateral epicondylitis, CS injection produced superior results within the brief follow-up time frame (4 weeks and 8 weeks post-treatment). Another systematic reviews and meta-analysis revealed that PRP injections demonstrated better pain and functional result (up to 24 weeks post-treatment follow up).[3] Limited information was found about lateral epicondylitis in Bangladeshi population.[4,8] However, no published article was found regarding the effectiveness of PRP and CS injection; both administered twice on 6 week apart, and evaluate pain and functional outcome. Hence, an attempt was made to find out the effectiveness of intralesional PRP and CS injection in terms of pain alleviation and functional status in the patient suffering from lateral epicondylitis.

Methodology

Study Design and Population: A single blind, single centered, randomized experimental study was conducted at Bangabandhu Sheikh Mujib Medical University (BSMMU), Physical Medicine and Rehabilitation department from March 2017 to February 2018. Comparison between 2 treatment options was evaluated. The patients with diagnosed lateral epicondylitis between the ages of 21 and 60, regardless of gender, VAS for pain >5, suffering more than 3 months attending outpatient's department of Physical Medicine and Rehabilitation were included in this research. Those patients were excluded who had arthritis, trauma to the elbow, previous elbow surgical procedure, severe anemia, an active systemic infection, bleeding disorder, infectious arthropathies, malignancy, radiculopathy, peripheral nerve deficit, use of antiplatelets 10 days before injection or NSAIDs 48 h before injection, steroid applied within 3 last weeks. According to the selection criteria, 42 patients were selected using the n=z2pq/d2 formula, where z=1.96, p=0.5, q=1-p, and d=0.15.

Randomization and Blinding: Participants were randomly assigned to either the PRP treatment (Group A) or corticosteroid group (Group B) using lottery. During the study, 3 patients withdrew themselves from the study due to post-procedure pain, and 9 patients were dropped out due to incomplete follow-up. All participants had given informed written consent prior procedure. Intervention/Allocation: Group A (n=15) patients received 4 ml of intralesional PRP injection. Group-A patients were sent to the Department of Transfusion Medicine to create platelet-rich plasma. About 20-25 mL of blood was drawn sterilely (the venipuncture procedure same as regular blood collection for pathology testing) and spun for 15 minutes at around 3,200 rpm in a centrifuge machine. The blood was then divided into its various components: platelets in the center, plasma at the top, and red blood cells at the bottom. A buffy coat was seen on top of the layer of red blood cells. About 4-5 mL of buffy coat was taken. Platelet-rich plasma was created using this buffy coat. The entire process didn't take more than 30 minutes. Group B (n=15) patients received 1 ml-2% lidocaine plus 1ml-40mg Triamcinolone acetonide in peppering technique over the most tender point of lateral epicondylar region of elbow. Both groups received activities of daily living (ADL) instructions, which included avoiding twisting movements, carrying heavy objects, and weight lifting using the affected limb. Additionally, both groups were instructed to take oral Paracetamol 500 mg twice daily for the entire treatment period if pain increased.

Follow up and Outcome Measures: Patients were assessed every 2 weeks interval up to 11 weeks (W11). 2nd dose of Intralesional PRP or corticosteroids injection was given on the lateral epicondylar region on 4th (W7) treatment visits. Patients were evaluated using a visual analogue scale (VAS)9 for pain (0=no pain; 10= maximum pain) and a patient-rated tennis elbow evaluation (PRTEE)10 at each visit where (Best Score= 0 Worst Score = 100).

Statistical Analysis: Statistical Packages for Social Sciences (SPSS-21) was carried out for statistical analysis. Categorical variables were described as frequencies, and continuous variables were described using the mean standard deviation (SD), median, and range; Paired t- test was done to find out the treatment effectiveness between the groups over time measured by VAS and PRTEE. Statistical significance was considered as a P value of 0.05 or below.

Ethical consideration: The research protocol was approved by the IRB (Institutional Review Board) of BSMMU; ID no BSMMU/2016/2380 on a meeting held on 15-12-2016. In this study precautions were taken to protect confidentiality of the participants. Information identifying the participant was kept to a minimum. There was no physical, psychological, and social risk to the patients. Privacy, anonymity, and confidentiality of data information identifying any patient were maintained strictly. Each patient enjoyed every right to participate or refuse or even withdraw from the study at any point of time. The study conforms to the code of ethics of the world medical association (Helsinki Declaration).

Results

In this study, there were 14(46.70%) male and 16(53.30%) were female and the ratio of men to women was 1:1.4. The patients' age, sex, height, weight, and elbow discomfort duration were all identical in both groups. Most of the participants were housewives from middle-class families. Majority of the participants complained that the character of pain was intermittent (73.3%), repeated activity (70.0%) was the most common aggravating factor and rest (93.3%) was the most common relieving factor (Table 1).

According to VAS, there was a noticeable improvement in both groups over time. From pretreatment week 1 (W1) through week 11, group A showed differences in progress every alternate week up to W 11. Whereas in group B, difference of improvement was found in every alternate week from pretreatment week 1 (W 1) up to week 9 (W 9). Nevertheless, there was no difference in improvement between W9 and W11 (Table 2)

It was discovered that there was no discernible difference in progress between the two groups for scores from W1 to W9. However, at the 11th week, group A showed a difference in improvement from group B shown in. (Table 3).

According to PRTEE, there was also a considerable improvement over time in both groups. By comparing the pretreatment W1 (immediately before the first intervention) score to the W11 score on a biweekly basis, both groups exhibited different levels of improvement over time shown in (Table 4).

In comparison between two groups, it was found that there was no significant difference in improvement up to W1 to W9 scores, but difference of improvement was found in group A than group B at 11th week (Table 5).

Table 1: Distribution of Evaluation of Pain (n=30)

Evaluation of Pain Pain Characteristics	Group A	Group B
• Persistent	5(33.33%)	3(20.0%)
• Intermittent	10(66.67%)	12(80.0%)
Exacerbating Factors		
• Heavy weight lifting	4(27.0%)	3(20.0%)
• Twisting action	1(6)	1(6.67)
• Recurring stress	10(67)	11(73.33)
Relieving Factors		
• Rest	14 (93.33)	14 (93.33)
• Taking NSAIDs	1(6.67)	1(6.67)
Severity Of Pain		
• Mild	1(6.67)	0
• Moderate	12 (80)	15 (100)
• Severe	2	0

Table 2: Treatment effectiveness in both group over time measured by VAS

Time-based scoring	Group A (n=15)			Group B (n=15)		
	Mean±SD	p-Value	95% CI	Mean±SD	p-Value	95% CI
W1 (Before 1st Intervention) Vs W3	6.20±2.14 vs 4.07± 1.62	0.000	1.476 to 2.791	5.87 ±1.72 Vs 2.80 ±1.74	0.000	2.143 to 3.990
W3 Vs W5	4.07 ± 1.62 vs 3.07± 1.33	0.001	0.487 to 1.513	2.80 ±1.74 Vs 2.93 ±1.75	0.546	-0.595 to 0.328
W5 Vs W7 (Before 2nd Intervention)	3.07±1.33 vs 2.73±1.03	0.096	-0.067 to 0.0734	2.93 ±1.75 Vs 3.13 ±1.92	0.271	-0.574 to 0.174
W7 (2nd Intervention) Vs W9	2.73±1.03 vs 1.40±0.63	0.000	0.92 to 1.675	3.13 ±1.92 Vs 1.67 ±0.90	0.001	0.746 to 2.188
W9 Vs W11	1.40±0.63 vs 0.53±0.51	0.000	0.512 to 1.221	1.67 ±0.90 Vs 1.27 ±0.88	0.054	-0.008 to 0.808

The outcomes are presented as mean and standard deviation(SD); N= Number of patients who took part in clinical study; W= Week, W1= 1st week, W3= 3rd week, W5= 5th week, W7= 7th week, W9= 9th week, and W11= 11th week

Table 3: Treatment Effectiveness between the Groups Over Time Measured by VAS (Mean±SD)

Groups	W1(Immediately before 1st injections)	W3	W5	W7 (Immediately before 2nd Injections)	W9	W11
Group A (n=15)	6.2±2.1	4.1±1.6	3.1±1.3	2.7±1.0	1.4±0.6	0.5±0.5
Group B (n=15)	5.8±1.7	2.8±1.7	2.9±1.7	3.1±1.9	1.6±0.9	1.2±0.8
P-value	0.651	0.089	0.836	0.516	0.334	0.003
95% CI	-1.21 to 1.88	-0.22 to 2.75	-1.22 to 1.48	-1.68 to 0.88	-0.83 to 0.30	-1.17 to -0.29

The outcomes are presented as mean and standard deviation (SD); N= Number of patients who took part in clinical study; W= Week, W1= 1st week, W3= 3rd week, W5= 5th week, W7= 7th week, W9= 9th week, and W11= 11th week

Table 4: Treatment Effectiveness in Both Group Over Time Measured by PRTEE

Time-point score	Group A (n=15)			Group B (n=15)		
	Mean±SD	p-Value	95% CI	Mean±SD	p-Value	95% CI
W1 (Immediately before 1st Injection) Vs W3	52.27±13.31 Vs 42.40±12.96	0.000	5.760 to 13.973	52.93±12.29 Vs 35.20±15.90	0.000	10.223 to 25.244
W3 Vs W5	42.40±12.96 Vs 34.27±11.58	0.000	5.373 to 10.893	35.20±15.90 Vs 31.07±14.53	0.003	1.640 to 6.626
W5 Vs W7 (Immediately before 2nd Injections)	34.27±11.58 Vs 24.13±7.80	0.000	6.720 to 13.546	31.07±14.53 Vs 32.00±14.20	0.444	-3.475 to 1.608
W7 (Immediately before 2nd Injections) Vs W9	24.13±7.80 Vs 12.93±5.54	0.000	8.494 to 13.906	32.00±14.20 Vs 19.87±10.99	0.000	8.988 to 15.279
W9 Vs W11	12.93±5.54 Vs 4.27±3.10	0.000	6.858 to 10.475	19.87±10.99 Vs 13.33±9.46	0.002	2.735 to 10.335

The outcomes are presented as mean and standard deviation (SD); N= Number of patients who took part in clinical study; W= Week, W1= 1st week, W3= 3rd week, W5= 5th week, W7= 7th week, W9= 9th week, and W11= 11th week

Table 5: Treatment effectiveness between the groups over time measured by PRTEE

Groups	W1(Immediately before 1st injection)	W3	W5	W7 (Immediately before 2nd injection)	W9	W11
Group A (n=15) Vs Group B (n=15) Mean±SD	52.2±13.3 Vs 52.9±12.2	42.4±12.9 Vs 35.2±15.9	34.2±11.5 Vs 31.0±14.5	24.1±7.8 Vs 32.0±14.2	12.9±5.5 Vs 19.8±10.9	4.2±3.1 Vs 13.3±9.4
P-value	0.865	0.232	0.554	0.079	0.061	0.002
95% CI	-8.943 to 7.610	-5.153 to 19.553	-8.124 to 14.524	-16.781 to 1.048	-14.243 to 0.376	-14.017 to -4.116

The outcomes are presented as mean and standard deviation (SD); N= Number of patients who took part in clinical study; W= Week, W1= 1st week, W3= 3rd week, W5= 5th week, W7= 7th week, W9= 9th week, and W11= 11th week

Discussion

The results of the current study demonstrated that intralesional platelet-rich plasma and intralesional corticosteroid treatment at the lateral epicondylar area of the elbow improved the subjective and objective measures of pain and functional indices. All the interventions were uneventful except mild discomfort and swelling, which was managed by ice therapy. However, none of them were found to have any sorts of infections. In the group A intervention with intralesional PRP, a statistically significant difference in improvement was seen from pretreatment W1 (immediately before the first intervention) to W11 score over time on a biweekly basis according to VAS and PRTEE. Similar research revealed that intralesional platelet-rich plasma significantly reduced pain levels using the visual analogue scale at 12 and 24 weeks compared to placebo (p value 0.001).[11] In additional research, it was shown that intralesional platelet-rich plasma injection, even with a single injection, demonstrated considerable pain alleviation and improvement in function as well as quality of life 6 months after intervention by PRTEE instrument.[12]

The patient's discomfort eased as the inflammatory process subsided and the damaged tendon began to repair due to various growth factors generated by platelets.[13,14] In this present study, the difference of improvement was discovered in terms of pain and functional parameters over time due to decline in inflammation, tissue regeneration and greater tensile strength.[15] Hence, PRP was fruitful since it lowers subjective and objective pain as well as functional outcome.

Recent studies on chronic lateral epicondylitis showed no evidence of inflammatory process rather fibro-elastic tissue and vascular invasion known as Angio fibroblastic tendinosis16. Therefore, local corticosteroid injection provided short time pain relief and functional improvement. The results of the current study shown that, over the brief follow-up period of up to 5 weeks, local corticosteroid injection significantly reduced VAS and PRTEE scores compared to PRP therapy. However, it was notable that the treatment with PRP regimen significantly lower VAS and PRTEE scores than steroid treatment at 7 week and subsequent follow-up.

In several clinical studies, individuals with elbow lateral epicondylitis were compared for activity and effectiveness between PRP and corticosteroid injection.[6,16] Epicondylitis was discovered to respond well to local corticosteroid injection. Nevertheless, these investigations revealed a short-term impact (2–6 weeks).[15,17]

Hence, the difference in improvement from pretreatment W1 (immediately before 1st Injection) to W11 score in every other week was found measured by VAS and PRTEE. The difference in improvement between the two groups was therefore significantly greater in group A, which was validated by other research.1,18,19

The PRTEE was a reliable, reproducible, and sensitive instrument for assessment of chronic lateral elbow tendinopathy. The PRTEE may become the standard primary outcome measure in research of tennis elbow.[20] A Visual Analogue Scale (VAS) is a reliable measurement instrument the amount of pain that a patient feels usually a horizontal line, 10cm in length patient marks on the line the point that they feel represents their perception of their current state.[21] Different studies from various corner of world are available regarding effect of various intervention methods based on multiple tools for lateral epicondylitis. Among Bangladeshi population, to search comparative effect between PRP and corticosteroid based on VAS and PRTEE were our target. We had an endeavor to find the comparison by this experimental study.

We have a few limitations. Smaller sample size, single blinded study, single centered study is few of them.

Conclusions

Intralesional PRP treatments injections demonstrated substantial improvement in pain and functional outputs compared with those of intralesional corticosteroids for lateral epicondylitis of elbow. To get firm results, higher power research with significantly bigger sample size is advocated.

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Contributions to authors: Conceptualized the research question, designed the study, and supervised the data collection and analysis: Islam MT; Contributed to the study design, conducted the statistical analyses, and drafted the manuscript: Mahjabin A; Provided critical feedback on the study design, data analysis, and manuscript, Rashid Al Mahmood M, Gomes LC, Shoma FK, Emran MA, Shakoor MA. All authors read and approved the finalize the manuscript for publication.

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Conflict of Interest: Authors declare no conflict of interest.

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