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Original Research Article

Effectiveness of ultrasound guided platelet rich plasma injection in comparison with extracorporeal shock wave therapy on improving pain and function in medial epicondylitis of elbow: a randomized controlled trial

Sagolsem Adarsh Singh*, Akoijam Joy Singh, Yumnam Nandabir Singh, Yumnam Ningthemba Singh, Pheiroijam Bhupes, Kongkham Purnimala Chanu, Laimujam Sobhasini Devi, Ramkumar R.

Department of Sports Medicine, Regional Institute of Medical Sciences, Imphal, Manipur, India

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***Correspondence:**
Dr. Sagolsem Adarsh Singh,
E-mail: sagolsem59@gmail.com

ABSTRACT

Background: Effectiveness of ultrasound guided Platelet Rich Plasma injection in comparison with extracorporeal shock wave therapy on improving pain and function in medial epicondylitis of elbow: A randomized controlled trial Objective was to determine the effectiveness of ultrasound guided Platelet Rich Plasma injection in comparison with extracorporeal shock wave therapy on improving pain and function in medial epicondylitis of elbow.
Methods: Randomized controlled trial was conducted on fifty-four patients with medial epicondylitis of elbow attending Sports Medicine OPD at RIMS, hospital, Imphal, were selected for this study and randomized into 2 treatment groups: platelet rich plasma injection and extracorporeal shock wave therapy. The outcome measures were visual analog scale and Mayo elbow performance score. For descriptive statistics mean, standard deviation and frequency were used. Students t-test and Chi square tests were used for analysis of different variables. A p-value <0.05 was taken as significant.
Results: The baseline characteristics of the patients in the control and intervention group were not statistically significant. At the end of 12 weeks and 24 weeks, there was statistically significant improvement in both mean difference of VAS (p=0.04) (p=0.03) and MEPS (p=0.00) (p=0.03) from baseline in both the groups but this improvement was significantly more in the PRP group.
Conclusions: Platelet rich plasma injection is superior to extracorporeal shock wave therapy on improving pain and function in medial epicondylitis at the end of 6 months.

Keywords: Medial epicondylitis, Platelet rich plasma, Extracorporeal shock wave therapy, Ultrasound guided, VAS, MEPS

INTRODUCTION

Epicondylitis is a common cause of elbow pain in athletes and the general population. It can occur both at the medial and lateral epicondyle with medial epicondylitis occurring less frequently than lateral epicondylitis.[1,2] Medial epicondylitis, also known as "golfer's elbow" or "thrower's elbow", refers to the chronic tendinosis of the flexor-pronator musculature insertion on the medial epicondyle of the humerus as a result of overuse or repetitive stress. The flexor-pronator muscle group is composed of the pronator teres and the common flexor

tendon, which includes tendons of the flexor digitorum superficialis, flexor carpi ulnaris, flexor carpi radialis, and palmaris longus. The flexor carpi radialis and the pronator teres are the most commonly involved tendons in medial epicondylitis.[3] Although termed epicondylitis, a more appropriate description, especially in a chronic setting, would be epicondylosis or epicondylalgia. Current literature shows that the underlying process appears to be degeneration and granulation tissue formation that is referred to as "angiofibroblastic hyperplasia or tendinosis" without the presence of a definitive inflammatory process. However, it should be noted, that there is no clear evidence that the early stages of the condition do not have an inflammatory component.[4,5]

Medial epicondylitis is primarily caused by repetitive strain from activities that involve frequent loaded gripping, forearm pronation, and/or wrist flexion. In the sports world, it can be seen in throwing athletes (baseball pitchers, javelin throwers), golfers, tennis players, bowlers, rock climbers, archers, and weightlifters.[6,7] Although it is often associated with athletes, this condition is also prevalent in the general population, commonly seen in carpenters, utility workers, butchers, and caterers. Medial epicondylitis is often precipitated by poor body mechanics, improper techniques, and/or inadequate equipment or tools.[8] Patients typically present with pain in the medial aspect of the elbow that is worse with activities, specifically gripping, throwing, and forearm flexion/pronation. Symptoms are normally relieved with rest. The pain most often develops gradually but can be acute in onset when due to trauma or injury.[9] Occasionally, patients will present with radiating pain into the forearm or wrist. More chronic presentations can also be associated with a decrease in grip strength.[10] Tenderness to palpation is generally most notable about 5 to 10 mm distal to the medial epicondyle at the insertion of the flexor-pronator mass.[11] The pain is generally aggravated with resisted wrist flexion and pronation, with resisted wrist pronation being the most sensitive exam finding.[12]

Diagnosis can be established clinically through history and physical examination, therefore further diagnostic investigation is not always necessary.[6] However, in cases where clinical presentation is not straightforward, imaging may help confirm the suspected diagnosis of medial epicondylitis as well as ruling out alternative etiologies. Findings on plain radiographs may consist of calcification in the flexor-pronator tendons or traction osteophytes.[10-13] Radiographs can be particularly helpful in patients who present with traumatic or acute onset of pain. Musculoskeletal ultrasound (US) evaluation has a sensitivity and specificity, 95.2% and 92% respectively, for the diagnosis of medial epicondylitis. The most common findings on ultrasound are focal, hypoechoic changes in the common flexor tendon, thickening of the tendon sheath, partial or full-thickness tears, neovascularization using Doppler, and cortical irregularities at the medial epicondyle.[14] Nonoperative management is the foundation for the treatment of medial epicondylitis. Initial pain relief is achieved with icing, especially after activities, and non-opiate analgesic medications, such as acetaminophen (first line) and nonsteroidal anti-inflammatories (NSAIDs).[9] Some patients benefit from bracing, which is done with a counterforce elbow strap or night splint. The counterforce strap should be placed about 2 cm distal to the medial epicondyle to provide compression and unload the tendon.[9] Corticosteroid injections have been shown to be helpful for symptom relief in the short term (up to 6 weeks post-injection), but there was no difference when compared to controls in the long term (3- and 12-months post-injection).[15]

A number of physical modalities have been tried in the management of epicondylitis. Extracorporeal shock wave therapy (ESWT) has been successfully used in soft-tissue pathologies like lateral epicondylitis, plantar fasciitis, tendinopathy of the shoulder and also in bone and skin disorders. Extracorporeal shock waves (ESWs) are transient pressure oscillations that propagated in three dimensions and directly stimulate the healing, neovascularization and suppression of the activity of nociceptors on the target tissue. ESW treatment can increase the neovessels at the normal tendon–bone junction through the release of growth factors, transforming growth factor (TGFb-1) and Insulin-like growth factor (IGF-I).

Clinical application of focal ESW demonstrated good short- to midterm results for the treatment of Lateral epicondylitis.[16-18] However conclusive evidence recommending ESWT as a treatment for Medial epicondylitis is still lacking.[19] Platelet rich plasma is a regenerative therapeutic modality derived by centrifuging autologous whole blood and has a platelet concentration higher than that of blood. The mechanism of action relies on releasing cytokines and growth factors from alpha granules. These enhance healing by stimulating cell proliferation, migration and differentiation, alongside interaction with the immune system, inflammation, and angiogenesis.[20] Autologous platelet-rich plasma (PRP) delivered into various tissues has been shown to enhance healing in wounds, tendons, and bones.[21] We believe that supplementing the natural healing process of epicondylitis with platelet rich plasma injection under ultrasound guidance for enhanced specificity would give better long-term results in the management of epicondylitis. To our knowledge there are no paper directly comparing the long-term efficacy and the clinical outcome of the focal ESW therapy and PRP injection. The aim of this study was to compare the efficacy of the two in improving pain and function among patients with medial epicondylitis.

Objectives

Objective was to determine the effectiveness of ultrasound guided platelet rich plasma injection in comparison with extracorporeal shock wave therapy on improving pain and function in medial epicondylitis of elbow.

METHODS

A prospective randomized controlled study to determine the clinical efficacy of ultrasound guided injection of PRP in comparison with extracorporeal shock wave therapy in the management of medial epicondylitis of elbow was carried out in the Department of sports medicine, regional institute of medical sciences, Imphal between August 2022 to January 2024. Fifty-four patients of both genders between 18-60 years of age suffering from medial epicondylitis were recruited for the study after obtaining written informed consent. The diagnosis was made on the basis of clinical presentation and ultrasound examination. Patients with duration of symptoms for greater than 3 months who were either on conservative treatment with analgesics and anti-inflammatory drugs or no treatment were enrolled in the study. A four-week washout period was given to all the patients on analgesics and anti-inflammatory drugs. Patients with history of any local injection, infection, trauma or fracture, nerve entrapment around elbow, bleeding disorder, thrombocytopenia and uncontrolled systemic illness were excluded from the study. Complete physical examination and relevant investigations including complete haemogram, fasting blood sugar (FBS) and plain X-ray of involved elbow were done. Selected patients were randomized to 2 groups (A and B) and block of four randomization was done. Group A study participants received a single injection of PRP (2 ml) under ultrasound guidance for greater accuracy. PRP was injected into and around the common flexon origin at the medial epicondyle of the humerus depending upon the site of hypoechogenecity under aseptic conditions. PRP was freshly prepared using the Double spin centrifuged method under aseptic condition. Group B study participants received three sessions of extracorporeal shock wave therapy (ESWT) at weekly interval. A focused electromagnetic shock wave device (EMS Swiss Dolorclast, Munich, Germany) was used. In each session, 2600 impulses were administered with a frequency of 8 Hz depending on patient's pain tolerance. According to the principle of clinical focusing, the area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximum pain level. No local anesthesia was applied. In both the groups only paracetamol (650 mg) tablets were allowed as rescue medication. Following the interventions the patients were called for follow up assessment after 1 week, 4 weeks, 12 weeks and 24 weeks.

Outcome measures

Pain intensity: This was assessed using the visual analog scale (VAS), a subjective assessment scale of perceived pain. VAS uses a numerical scale ranging from 0 to 10, where 0 indicates no pain and 10 indicates maximum possible pain. Assessment was done at 4 weeks, 12 weeks and 24 weeks post intervention. Functional outcome: Functional outcome was measured using Mayo Elbow Performance Score at baseline and in all three follow up visits. The MEPS is a subjective assessment scale used to test the limitations, caused by pathology, of the elbow during activities of daily living (ADL). This specific test uses 4 subscales: pain, range of motion, stability and daily function. Single blinding was done where assessors were blinded. Patients of both the groups underwent rehabilitation programs that focused on stretching and strengthening exercises of elbow flexors. The participants were told that the exercises may be painful but not to exceed an intensity of 4/10. As the pain eases over time, load is progressively increased by adding weights to a backpack.

Statistical analysis

Collected data were checked for completeness and consistency. Statistical analysis was done using IBM-Statistical Package for the Social Sciences (IBM-SPSS) Version 21. For descriptive statistics mean, standard deviation and frequency were used. Continuous variables (age, duration of symptoms, VAS, MEPS) were analysed by student's t-test. Categorical variables (gender, side of affection) were analysed using Chi-square test. Within the group comparison (baseline and follow up data of each group) was done by repeated measures ANOVA test. Between the group comparison (intervention group and control group) was analysed using student's t-test, $p<0.05$ was taken as significant.

RESULTS

The baseline characteristics of the patients in the control and intervention group were not statistically significant (Table 1).

Table 1: Comparisons of background and baseline characteristics between the between PRP group (study) and ESWT group (control).

Characteristics	Groups		P value
	Intervention	Control	
Mean age (years)	32.07±5.64	33.38±4.60	0.437*
Mean duration of symptoms (months)	6.72±1.73	6.27±1.64	0.110*
Gender			
Male	16	15	0.870**
Female	11	12	
Side of affection			
Right	18	17	0.608**
Left	9	10	

*independent t test, **Chi-square test, $p<0.05$ as significant

Outcome measures at baseline were not statistically significant (Table 2). Within the group comparison showed no significant improvements in both VAS and MEPS at 4 weeks, but significant improvement was noted at 12 weeks and 24 weeks follow up (Table 3). Between the groups comparison at the end of 4 weeks showed that there was no statistically significant difference between

the groups in both mean difference of VAS (p=0.10) and MEPS (p=0.16) from baseline.

Table 2: Comparisons of baseline dependent variables between the between PRP group (study) and ESWT group (control).

Characteristics	Groups		P value*
	Intervention (Mean±SD)	Control (Mean±SD)	
VAS	6.78±0.98	6.67±1.018	0.96
MEPS	64.36±8.32	62.47±7.35	0.069

*Independent t test, p value <0.05 taken as significant

However, at the end of 12 weeks and 24 weeks, there was statistically significant improvement in both mean difference of VAS (p=0.04) (p=0.03) and MEPS (p=0.00) (p=0.03) from baseline in both the groups.

DISCUSSION

Epicondylitis of the elbow is a common problem affecting both athletes and the general population alike. Medial epicondylitis even though less reported than lateral epicondylitis can be equally troublesome and can severely hamper an individual with his activities of day to day living. Nonoperative management is the foundation for the treatment of medial epicondylitis. Initial pain relief is usually achieved with icing, especially after activities, and non-opiate analgesic medications, such as acetaminophen (first line) and nonsteroidal anti-inflammatories (NSAIDs). Some patients may benefit from bracing, which is done with a counterforce elbow strap or night splint. However unfortunately there are no clear guidelines available for the treatment of medial epicondylitis. For many years, injection of corticosteroid has been the preferred treatment of patients with pain in medial epicondylitis.

Table 3: Within the group comparison of outcome measures in both groups.

Outcome measures	Study groups	Baseline	4 weeks	12 weeks	24 weeks
VAS	**Intervention (PRP)**	6.78±0.98	4.51±0.799	3.15±0.912	1.53±0.857
	P value*		0.45	0.02	0.00
	Control (ESWT)	6.67±1.01	3.99±0.780	3.24±0.689	2.89±0.884
	P value*		0.26	0.02	0.01
MEPS	**Intervention (PRP)**	64.36±8.32	73.14±6.81	84.14±7.40	95.12±9.50
	P value*		0.19	0.00	0.00
	Control (ESWT)	62.47±7.35	74.97±6.76	77.17±7.61	86.42±9.87
	P value*		0.41	0.03	0.00

*Repeated measures ANOVA, p<0.05 is taken as significant

Table 4: Comparisons of mean difference changes from baseline in outcome measure between prolotherapy group (study) and ESWT group (control).

Outcome measure	Follow up	Intervention group (Mean±SD)	Control group (Mean±SD)	P value*
VAS Score	4 weeks	1.48±0.82	3.17±1.33	0.10
	12 weeks	3.81±1.92	3.34±1.31	0.04
	24 weeks	5.20±1.17	3.51±1.15	0.03
MEPS	4 weeks	-6.48±3.85	-10.48±7.41	0.16
	12 weeks	-19.48±6.66	-11.68±8.14	0.00
	24 weeks	-36.34±9.07	-16.51±10.55	0.03

*Independent t test, p value <0.05 taken as significant

Earlier studies suggested greater benefits of corticosteroid injection compared to NSAIDs, but the same cohort of patients demonstrated no difference in pain control and outcomes at 12 months.[22] More recent studies suggested that corticosteroid injections demonstrated only short-term relief and that these patients may have more pain and dysfunction at longer follow-up compared to other patients treated with conservative measures.[23,24] Smidt et al showed high frequency of relapse and recurrence with corticosteroid injection for LE because the inhibitor processes of cortisone may lead the intra-tendinous injection to deleterious long-term effects with permanent structural changes and tendon atrophy.[24] Extracorporeal shock wave therapy (ESWT) was first introduced to disintegrate renal stone or common duct stone in 1970's and started being used in treatments of various musculoskeletal pain in 1990's. However, its mechanisms or established treatment guidelines remain highly controversial.[25-27] In the treatment of epicondylitis of the elbow, it has been explained that there are analgesic effects secondary to overstimulation, changes in permeability of nerve cell membrane formation in enthesis and neovascular but none of these have proven to be clear mechanisms through experiments.[28] In a study by Lee et al to evaluate the effectiveness of extracorporeal shock wave therapy for patients newly diagnosed with lateral or medial epicondylitis, compared to local steroid injection, it was

concluded that ESWT improved patient symptoms as much as the local steroid injection.[28] Thereby suggesting, ESWT can be a useful treatment alternative to corticosteroid injections. In a report by Grala et al ESWT seemed to be ineffective for the management of chronic Medial epicondylitis non-responsive to traditional conservative therapy.[28,29] There are numerous reports on the use of ESWT in epicondylar (mainly lateral) soft tissue problems, but the results are inconclusive.[30,31] The methodology varies greatly (number of sessions, energy doses, positioning of the patient, methods of evaluation), so comparisons and conclusions are difficult to make.

PRP is an autologous blood-derived product which has been used in humans for its healing properties attributed to the increased concentrations of autologous growth factors and secretory proteins that may enhance the healing process on a cellular level. PRP contains a 3 to 5-fold increase in growth factors concentration and is associated with enhancement of healing process. PRP has been demonstrated as a potent agent for tissue healing in chronic wounds, tendinitis, and even bone. A possible explanation for the long-lasting effect of PRP in chronic tendinopathy is that it promotes revascularization and enhances healing at the microscopic level.[21,32,33] In a study by Varshney et al to evaluate the effectiveness of PRP injection in epicondylitis, it was concluded that one single injection of autologous PRP improves pain and function more than steroid in cases of elbow epicondylitis, and these improvements were sustained over a long period of time with no complications.[34] Peerbooms et al compared a single PRP injection and corticosteroid injection in patients who failed nonoperative measures and demonstrated significant pain reduction and increased function with PRP injection therapy. Authors obtained 73% of success rate.[35] In a similar study Mishra et al published a prospective randomized controlled trial of 230 patients and highlighted a meaningful improvement in the clinical outcome in patients treated with leucocyte-enriched PRP for LE after 24 weeks. The success rate of this study was 82.1%.[35] Both extracorporeal shock wave therapy and platelet rich plasma injection are being increasingly used as an alternative to corticosteroid injection in the management of medial epicondylitis. However, there is very little data and to our knowledge no study directly comparing the effectiveness of the two modalities in Golfer's elbow. This randomized study was designed with the aim to determine the effectiveness of ultrasound guided PRP injection in patients with medial epicondylitis in comparison with ESWT. Our study found that both the treatment options seem to be safe and effective in the reduction of pain as measured by VAS and improving function as assessed using the Mayo elbow performance score in medial epicondylitis. However, the improvement in both pain and function was significantly more in the PRP group at 6 months follow up. We believe that the presence of various growth factors in PRP which are released almost immediately post injection and continues over a period of weeks provides both short-term as well as long-term improvement in both pain and function without any limitations thus thereby allowing an individual to perform activities of daily living without discomfort and also reducing the time for athletes away from training or competitive sports.

Limitations

This study has the following principal limitations: lack of a placebo control group, and although the assessment was blinded, there was no way to blind the patients to the treatment. Therefore, it is possible that their awareness of the treatment modality may have had some effect on their perception of their response to the treatment.

CONCLUSION

Platelet rich plasma injection is superior to extracorporeal shock wave therapy on improving pain and function in medial epicondylitis at the end of 6 months.

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