

A Randomised Control Trial For Analysing Effectiveness Of Corticosteroid Versus Platelet Rich Plasma Injection In Tennis Elbow

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Abstract

Introduction: Lateral elbow eFigondylar tendinosis or tennis elbow (TE) is a common condition occurring at the common extensor tendon that takes origin from the lateral eFigondyle in patients whose activities require repetitive movements or strong gripping. It causes functional impairment and pain in daily activities. Even though it has been termed tennis elbow, it affects non-athletes rather than athletes. **Materials and Methods:** The study was conducted in the Department of Orthopaedics, Maharajah's Institute of Medical Sciences, Vizianagaram over a period of 23 months from Jan, 2019 to Dec, 2020. Subjects were recruited from patients presenting in Orthopaedics OPD, Maharajah's Institute of Medical Sciences, Vizianagaram (with a primary diagnosis of lateral eFigondylitis or Tennis Elbow) after obtaining written informed consent. Diagnosis of lateral eFigondylitis was made on clinical grounds. The type of study was Randomised Experimental Study with a sample size of 60 consecutively reporting subjects in the OPD. Study subjects were systematically and randomly allocated into two groups of 30 each (Group A and Group B). **Results:** The present study includes subjects with a primary diagnosis of lateral eFigondylitis (Tennis elbow). The recruited subjects were randomly allocated into two treatment groups i.e. Corticosteroid injection and Autologous Platelet Rich Plasma injection. Pain and elbow function was assessed by VAS (Visual analogue scale) and Modified Mayo Performance Index for Elbow. Efficacy of both the interventions was compared at three different time frames i.e. 1, 2 and 6 months. This study was conducted in the Department of Orthopaedics, Maharajah's Institute of Medical Sciences, Vizianagaram over a period of 23 Months year. The study comprised of 60 subjects with 30 patients in each group. **Conclusion:** In conclusion, this study describes the comparison of an autologous platelet concentrate with commonly used corticosteroid injection, as a main therapy for lateral eFigondylitis in patients who have failed nonoperative treatment. It reveals that a single injection of concentrated autologous platelets improves pain and function more so than corticosteroid injection. More importantly these improvements were profound and sustained over longer periods of time as compared to corticosteroid injection.

Keywords: Lateral elbow eFigondylar tendinosis, VAS, tennis elbow

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Introduction

Lateral elbow eFigondylar tendinosis or tennis elbow (TE) is a common condition occurring at the common extensor tendon that takes origin from the lateral eFigondyle in patients whose activities require repetitive movements or strong gripping[1,2]. It causes functional impairment and pain in daily activities[3]. Even though it has been termed tennis elbow, it affects non-athletes rather than athletes[4]. It is shown to be an incidence of 4-7 per 1000 per year in the general population, with a peak between the ages of 35 - 54 years, with a mean age of around 42 years. Five different findings have been reported in the literature with respect to gender prevalence; however, no distinct prevalence is evident. The right arm has been found to be predisposed to lateral eFigondylitis. In an epidemiologic study, it was reported that 87% of the cases involved the dominant arm. Tennis elbow has numerous etiologies including repetitive wrist turning or hand gripping, tool usages, shaking hands, and twisting movements that may exceed tissue capacities and lead to micro-trauma and over usage of wrist extensor musculature leads to injury and enthesopathy

usually around the lateral eFigondyle that commonly causes the condition[6]. The presentation of TE can be in the form of acute, intermittent, subacute or chronic pains and accompanied possibly with weakness in the forearm and on physical examination, there is tenderness without swelling along the extensor tendons at or just below the lateral eFigondyle. Elbow range of motion (ROM) is normal. On affected side grip strength is diminished[7]. Histologic findings in chronic cases confirm that lateral eFigondylar tendinosis is the failure of a normal tendon repair mechanism associated with angiofibroblastic degeneration[1-3] and it is not an inflammatory condition. There are many varieties of treatment options for this common condition[8,9]. The treatment is initially conservative. Numerous methods are shown to treat tennis elbow, including rest, anti-inflammatory medications, bracing, physical therapy, iontophoresis, extracorporeal shockwave and botulinum toxin. Injections of corticosteroids, dry needling and various surgical techniques have been incorporated in refractory cases [9,10]. However, these traditional therapies do not alter the tendon's less healing properties secondary to poor vascularization [9]. Modalities such as local corticosteroid injection have focused on suppressing inflammatory process that does not exist. A recent review article concluded that short term outcome (6 weeks) with corticosteroid injection was better as compared to placebo, local anesthetics and other conservative treatments. For intermediate (6 weeks - 6 months) and long term outcomes (>6 months), no clinically relevant or statistically significant results in favour of corticosteroid injections

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are present. So it is not possible to draw a firm conclusion on the effectiveness of corticosteroid injection. Given the inherent nature of the tendon, new treatment options including Platelet Rich Plasma (PRP), autologous blood, prolotherapy, and extracorporeal shockwave therapy are focused at inducing inflammation rather than suppressing it [1,10]. Platelet-rich plasma (PRP) contains important growth factors like Platelet-derived growth factor, Transforming growth factor β 1, Basic vascular endothelial growth factor, fibroblastic growth factor and epidermal growth factor which have been shown to play an important role in all phases of healing. Hence, we conducted a study to investigate the effectiveness of PRP compared with local corticosteroid injection on chronic lateral eFingondylitis & the possible benefit of one method over the other.

Aims and Objectives

To evaluate and compare the effectiveness of platelet-rich plasma and corticosteroid injection in the management of tennis elbow.

Materials and Methods

The study was conducted in the Department of Orthopaedics, Maharajah's Institute of Medical Sciences, Vizianagaram over a period of 23 months from Jan, 2019 to Dec, 2020. Subjects were recruited from patients presenting in Orthopedics OPD, Maharajah's Institute of Medical Sciences, Vizianagaram (with a primary diagnosis of lateral eFingondylitis or Tennis Elbow) after obtaining written informed consent. Diagnosis of lateral eFingondylitis was made on clinical grounds. The type of study was Randomised Experimental Study with a sample size of 60 consecutively reporting subjects in the OPD. Study subjects were systematically and randomly allocated into two groups of 30 each (Group A and Group B).

Selection of Subject: Two groups of 30 patients each were made. Patients in group 'A' were subjected to local corticosteroid injection and in group 'B' to autologous platelet-rich plasma injection.

Inclusion criteria:

- Pain over the lateral eFingondyle.
- Tenderness on direct palpation over the lateral eFingondylar region.
- Pain around the elbow on resisted wrist extension and supination.
- With the duration of symptoms more than three months.
- Pain severity with minimum score of 5 (based on 10 scales Visual Analogue Scale)
- Age > 18 years and < 60 years.
- Provided informed consent.

Exclusion Criteria

- Any previous history of trauma or surgery to the concerned elbow.
- Age < 18 years and > 60 years.
- Any local infection at the site of the procedure.
- Cervical radiculopathy.
- Systemic disorders like Diabetes, Rheumatoid arthritis, any platelet dysfunction syndrome or coagulopathy.
- Any recent history of aspirin or aspirin-like drug intake.
- Platelet count < 1.5 lakh/cu mm.
- Patients are not willing to participate in study.

Study tools: Structured study instruments (case reporting form) was developed, and used to generate data and assessment was done by:

- Standard elbow examination system - Modified Mayo Clinic Performance Index for the Elbow.
- Visual Analogue Scale (VAS) for pain

Study Protocol: Two groups, A (corticosteroid) and B (platelet-rich plasma) were made.

Subjects were randomly and systematically allocated into the two groups and baseline scoring was done.

Procedure: The procedure was carried out under all aseptic precautions. Elbow was prepared with povidone-iodine scrub and spirit and then draped.

Corticosteroid Group: (A) Patients in the steroid treatment group were treated with 2ml of methylprednisolone acetate (40mg) with 1ml of 2% lignocaine hydrochloride. The injection was administered with a standard 20-gauge needle into the most tender area around the eFingondyle.

Platelet Rich Plasma Group: (B)

3 ml of the extracted platelet rich plasma was injected into the most tender area around the eFingondyle with a standard 20-gauge needle.

Position: Injection was administered in sitting position with arm directed at patient's side and elbow flexed and forearm supinated with the surgeon's thumb on the most tender point.

Immediately after the injection the patient was kept in a supine position for 15 minutes, and then sent home with instructions to limit their use of the arm for at least 24 hrs and an arm sling was provided. Procedure was performed and the patient was called for follow up after 1st, 2nd and 6th month and was assessed through the same examination system and scores (Modified Mayo Clinic Performance Index For The Elbow and Visual Analogue Scale For Pain) were recorded.

Preparation of Autologous Platelet-rich Plasma:

PRP Preparation:

- 10 ml of blood was drawn from the patient and introduced into two EDTA containing tubes 5ml of blood in each tube and then centrifuged.
- The first spin was at 1800 rpm for 15 min to separate erythrocytes and white blood cells from other blood components
- Second spin was at 3500 rpm for 10 min for further concentration of platelets.
- The supernatant platelet poor plasma is discarded and 1 ml of concentrated platelets was obtained.
- The platelet counts for PRP and unprocessed blood were assessed. The PRP showed mean concentration of 3-4 \times platelet compared with whole blood.

Statistical Analysis: Patients were randomized, after they were deemed eligible and had provided informed consent, by a computer using block randomization. Interpretation and analysis of data were done by analytical method. SPSS-16.0 (SPSS Inc Chicago, Illinois, United States of America) was used for data analysis. The qualitative data was represented in the form of frequency and percentage. The quantitative data were expressed in terms of Mean \pm SD. Independent t-test was used to compare the means of the study groups. The level of statistical significance was set at $P < .05$. The assessors filling out the questionnaire of Modified Mayo scores and assessing VAS scores, also the statistician were same and blinded to the group of the patients.



Fig 1: Blood drawn from the Patient



Fig 2: Centrifuging the whole blood



Fig 3: Centrifuging Machine

Fig 4: After First Spin



Fig 5: After Second Spin



Fig 6: Preparing the Injection site

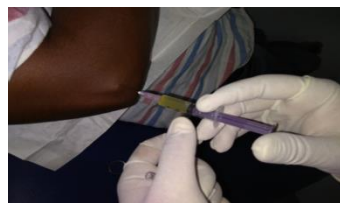


Fig 7: Injecting PRP into lateral EFigondyle



Fig 8: Injecting steroid into lateral eFigondyle

Results

The present study includes subjects with a primary diagnosis of lateral eFigondylitis (Tennis elbow). The recruited subjects were randomly allocated into two treatment groups i.e. Corticosteroid injection and Autologous Platelet Rich Plasma injection. Pain and elbow function was assessed by VAS (Visual analogue scale) and

Modified Mayo Performance Index for Elbow. Efficacy of both the interventions was compared at three different time frame s i.e. 1, 2 and 6 months. This study was conducted in the Department of Orthopedics, Maharajah’s Institute of Medical Sciences, Vizianagaram over a period of 23 Months year. The study comprised of 60 subjects with 30 patients in each group.

Table 1: Sex wise distribution of subjects (n=60)

Sex	Number of subjects	Percentage
Male	25	42%
Female	35	58%

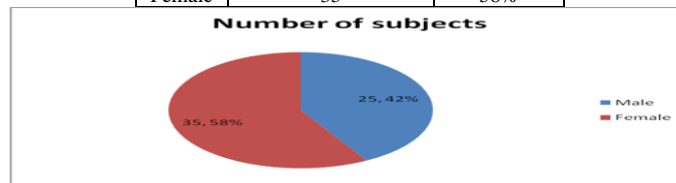


Fig 9: Number of patients included in the study (n=60)

Out of 60 subjects evaluated, 25 were male (42%), and 35 were female. (58%) (Fig 1).

Table 2: Involved elbow distribution

Side	Number of subjects	Percentage
Right	44	74%
Left	16	26%

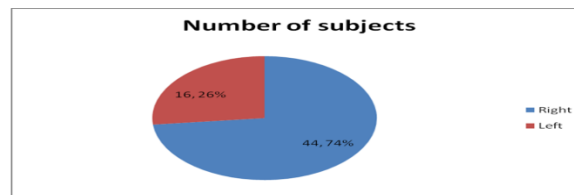


Fig 10: Involved elbow distribution (n=60)

There were a total of 60 patients evaluated; there was the involvement of right elbow in 44 (74%) patients. In the rest 16 (26%) patients, left elbow was involved d (Fig 10)

Table 3: Age wise distribution (n=60)

Age group	Number of subjects	Percentage
18-40 yrs	21	35%
41-60 yrs	39	65%

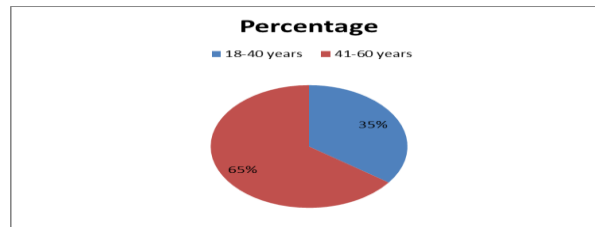


Fig 11: Age-wise distribution of patients (n=60)

On age-wise distribution of the patients, it was found that the maximum number of patients belonged to the age group 41 - 60 years i.e. 39 (65%). The rest 21 (35%) belonged to 18 – 40 years of age group (Fig 11). The mean age of the patients in the study was 42.5 years

Table 4: Baseline scores in the study groups

	Group A (Steroid) (Mean ± SD)	Group B (PRP) (Mean ± SD)	p Value
Pre-procedure VAS	7.86 ± 1.22	8.36 ± 1.09	0.117 ^{NS}
Pre procedure MAYO	64.88 ± 6.95	61.75 ± 7.01	0.085 ^{NS}

NS- Not significant

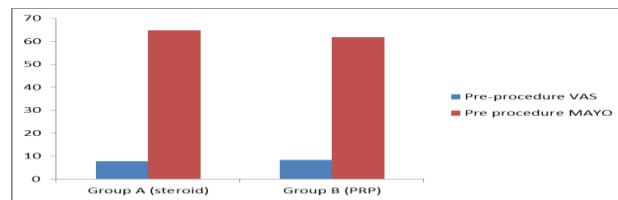


Fig 12: Baseline MAYO & VAS scores in the study groups

Prior to the intervention, pain and function of elbow were assessed by VAS and Modified Mayo Clinic Performance Index for the Elbow. The Mean ± SD of the scores in the study groups were compared. The p-value was found to be 0.117 and 0.085 in pre-procedure VAS and MAYO respectively. Both the p values were not statistically significant.

Table 5: Comparison of the pain score (VAS) in the study groups

	Group A (Steroid) (Mean ± SD)	Group B (P RP) (Mean ± S D)	p Value
1 Month FU (t = 1 month)	2.36 ± 1.18	2.46 ± 0.93 7	0.608 ^{NS}
2 Months FU (t = 2 months)	1.33 ± 0.80	1.56 ± 0.93 5	0.535 ^{NS}
6 Months FU (t = 6 months)	4.60 ± 1.54	.76 ± 1.63	<0.001 ^{HS}

NS-not significant, HS-highly significant, FU-follow up

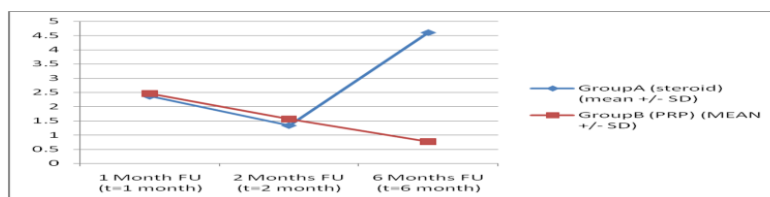


Fig 13: Comparison of the pain score (VAS) in the study groups

The pain score was calculated for the study groups after the intervention at three different time frames; t=1 month, t= 2 months and t= 6 months. The VAS score means ± SD were compared using the t-test of independent means at the three time frames. The p value was found to be > 0.05 in 1 month and 2 month follow up. Thus, PRP offered no superior.

Benefit over Steroid in short term follow up. The p value was statistically significant when the mean ± SD of the VAS score was compared at 6 months follow up which proved that PRP offered better analgesia as compared to steroid on long term follow up (Fig 13).

Table 6: Comparison of MAYO Elbow scores in the study groups

	Group A (Steroid) Mean ± SD	Group B (PRP) Mean ± SD	p Value
1 Month FU (t = 1 month)	78.90 ± 4.57	79.08 ± 4.96	0.781NS
2 Months FU (t = 2 months)	86.91 ± 10.41	87.06 ± 6.35	0.597NS
6 Months FU (t = 6 months)	62.65 ± 7.26	94.58 ± 9.82	<0.001HS

S-not significant, HS-highly significant, FU-follow up

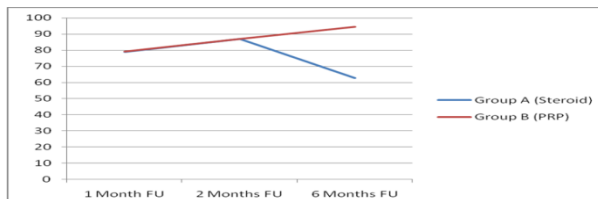


Fig 14: Comparison of the MAYO Elbow scores in the study groups

The mean ± SD of the MAYO Elbow score was compared at three different time frames. On short term follow up i.e. t = 1 month and t = 2 months, the p value was 0.781 and 0.597 respectively. Both the p values were not statistically significant. However at t = 6 months, the

p value was < 0.05, this was statistically significant. Hence PRP proved to be a better mode of treatment for lateral epicondylitis on long term follow up when compared to steroid (Fig 14).

Table 7: Complications in the study groups

	Steroid	PRP
Post injection exacerbation of pain	3	8
Local skin atrophy	2	0
Infection	0	0

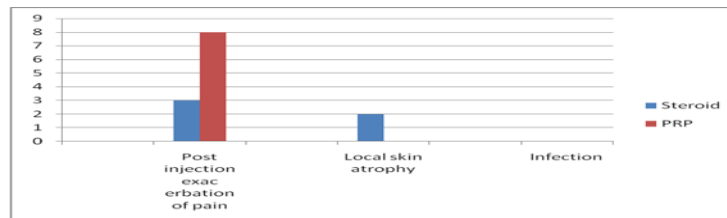


Fig 15: Complications in the study groups

Complications associated with the intervention were as follows: Post injection exacerbation of pain was seen in 3 out of 30 patients in the steroid group and 8 out of 30 patients in the PRP group. Only 2 patients had local skin atrophy in the study population. All these patients were in the steroid group. No patients reported elbow stiffness, infection, reflex sympathetic dystrophy, post-injection flare, facial flushing, neurovascular damage or tendon rupture or other untoward complications.

Discussion

Lateral epicondylar tendinosis is a common problem with many possible treatments. Quick cessation of symptoms is important to patients and is economically advantageous. If neither rest nor simple treatment provides a satisfactory remedy, a patient may pursue several other options.

Corticosteroid injections have also been used extensively for this problem, but studies show that there is conflicting evidence about their efficacy. Jobe and Cicotti also concluded that superficial injection of corticosteroid may result in subcutaneous atrophy and

that intratendinous injection may lead to permanent adverse changes within the ultra structure of the tendon. Despite these issues, corticosteroid is still widely used. Platelet-rich plasma (PRP) is promoted as an ideal autologous biological blood-derived product that can be exogenously applied to various tissues where it releases high amounts of platelet-derived growth factors that enhance wound healing, bone healing and tendon healing[2]. In addition, PRP contain high antimicrobial properties that may contribute to the prevention of infections. When platelets become activated, growth factors are released and initiate the body's natural healing response.

The present study entitled "A comparative study to evaluate the results of corticosteroid versus autologous platelet rich plasma injection locally for the treatment of lateral epicondylitis (Tennis Elbow)" was conducted in the Department of Orthopaedics, Maharaja's Institute of medical sciences Vizianagaram. A total of 60 patients were included in our study. Patients were randomly allocated into two intervention groups i.e. Group A-Corticosteroid and Group B- Platelet Rich Plasma. The mean age of patients in the study was

42.56 years. Age ranged between 19 and 60 years. Maximum number of patients were seen in the age group of 41-60 years. Mean age was observed to be 40.5 yrs in a study conducted by Omar et al. Rahman et al in their study observed a peak incidence of eFigondylitis in the age group of 45- 54 years. A female occurrence was observed in this study regardless of the group allocated. In the present study, 35(58%) subjects were females and 25 (42%) were males. Findings were coherent with the epidemiological study conducted by Shiri Rahman et al and Aziza Sayed Omar et al. Majority of the cases in the study had symptoms in their right elbow. 44 (74%) cases had their right elbow involved while 16 (26%) had their left elbow involved. In a study by, Peerboom et al 63% patients had lateral eFigondylitis on the right side. In most cases the dominant side was involved. In this study baseline pain and function scores of the 2 groups i.e. corticosteroid and platelet rich plasma were found to be comparable. The mean VAS score before intervention in the steroid group was 7.86 ± 1.22 while in Platelet rich plasma group was 8.36 ± 1.09 , with a p value of 0.117 which was not significant. Similar observation was made by Peerbooms et al. In their study the mean VAS score prior to intervention was 65 ± 13.8 and 70.1 ± 15.1 (on a scale of 0-100) in control and PRP group respectively. In a similar study by Mishra et al initially the patients had a Pre VAS score of 80. Mean MAYO elbow score before intervention in steroid and PRP group were 64.88 ± 6.95 and 61.75 ± 7.01 respectively with a p value of 0.085 which was also not significant. Pre MAYO score in the study conducted by Mishra et al was 50.3. At the first follow up i.e. 1 month, there was no statistically significant difference between the two groups with respect to Visual Analogue Scale score. The mean VAS score at 1 month follow up was 2.36 ± 1.18 in steroid group while that in PRP group was 2.46 ± 0.935 , with a p value of 0.608. The observation was not statistically significant. At the end of 2 months, the mean VAS score in steroid and PRP group was 1.33 ± 0.80 and 1.56 ± 0.935 respectively with a p value of 0.535 which was not statistically significant. This showed that both steroid and autologous PRP showed similar response in the short term follow up. Similar observations were made in the study conducted by Omar et al which showed a significant difference in VAS scores at first and second visit between both groups relative to the baseline scores but comparison of scores changes among two groups of patients showed insignificant difference relative to the outcome measures evaluated. Comparable observations were also made in studies conducted by Peerbooms et al and Mishra et al, who observed that both steroid and autologous PRP showed good response for pain resolution in the short term follow up. When pain was assessed after 6 months of intervention, it was found that the mean VAS score in steroid group was 4.60 ± 1.54 while that in the PRP group was 0.76 ± 1.63 . The p value came out to be $< .001$ which was statistically highly significant. When elbow function was assessed in the present study, it was found that, at 1 month follow up there was no significant difference between the two groups. Mean MAYO score of steroid group after 1 month was 78.90 ± 4.57 while that of PRP group was 79.08 ± 4.66 with a p value of 0.781. After 2 months of intervention, the mean MAYO score in steroid and PRP group was 86.91 ± 10.41 and 87.06 ± 6.35 respectively. The p value was 0.535, which was not statistically significant.

At the end of 6 months statistically significant difference was observed between the MAYO scores of the two groups. Mean MAYO score in steroid group was 62.65 ± 7.26 while that in the PRP group was 94.58 ± 9.82 . The p value came out to be $< .001$ which is highly significant. Similar results were obtained by Mishra et al in their prospective study where they compared the efficacy of local corticosteroid injection versus buffered platelet-rich plasma in chronic elbow tendinosis. They concluded that treatment with buffered platelet rich plasma offered long term results when compared to corticosteroid. Complications were also associated with

Conflict of Interest: Nil Source of support: Nil

this study. Post injection exacerbation of pain was seen in 3 patients treated with steroid and 8 patients treated with autologous PRP, which was relieved by oral analgesics for 5-7 days. 2 patients in the steroid group had local skin atrophy after the injection which required no treatment. No other complications such as elbow stiffness, infection, reflex sympathetic dystrophy, post-injection flare, facial flushing, neurovascular damage or tendon rupture were observed. Based on the evidences of study, it can be concluded that when comparing three active treatments, PRP injection was the best and foremost treatment for reducing pain VAS after increasing pressure threshold (PPT) both within and after 2 months. However, Autologous blood injection had the highest risk of adverse effects (injection site pain and skin reaction). Both the PRP and corticosteroid groups had shown better pain relief at 3 and 6 months as compared to the normal saline group ($P < 0.05$), but at 6 months followup, the PRP group had statistically significant better pain relief than corticosteroid group. A total of 7 randomized controlled trials (RCTs) involving 515 patients were finally carried out in our study. The present meta-analysis indicated that PRP injection yielded statistically significant superior in pain scores and elbow joint function at a 6-month follow up compared with local corticosteroid injection. No significant difference was identified between two groups regarding the post-injection adverse events.

Conclusion

In conclusion, this study describes the comparison of an autologous platelet concentrate with commonly used corticosteroid injection, as a main therapy for lateral eFigondylitis in patients who have failed nonoperative treatment. It reveals that a single injection of concentrated autologous platelets improves pain and function more so than corticosteroid injection. More importantly these improvements were profound and sustained over longer periods of time as compared to corticosteroid injection.

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