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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 epicondylar tendinosis or 'tennis elbow' is a condition occurring at the common extensor tendon origin from the lateral epicondyle in patients whose activities require repetitive movements or strong gripping. The treatment is initially conservative. Numerous methods are used 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 cases that do not respond to non-operative treatment. This study aimed to examine the effectiveness of platelet rich plasma (PRP) injection in comparison with other treatments of chronic lateral elbow epicondylar tendinosis.

Methods

The study was conducted in the Department of Orthopaedics, Maharajah's Institute of Medical Sciences, Vizianagaram, India over a period of 23 months from Jan, 2019 to Dec, 2020. The study was a randomised control trial (RCT) with a sample size of 60 subjects consecutively reporting to the outpatient department for treatment and at 1, 2 and 6 month follow-ups. Study subjects were systematically and randomly allocated into two groups of 30 each: Group A received corticosteroid injection and Group B received platelet rich plasma (PRP) injection. Interpretation and analysis of data was carried out using SPSS version 16.0.

Results

Pain score (VAS score) and elbow functional score (MAYO elbow score) were compared between the groups. There was no statistically significant difference between the groups prior to injection or at short term (1 month and 2 month) follow up but after 6 months, the PRP group had lower pain scores and elbow function scores compared with the steroid group. These improvements were profound and sustained over longer periods of time when compared with corticosteroid injection.

Conclusion

The study concludes that a single injection of concentrated autologous platelet rich plasma improves pain and function more so than corticosteroid injection and thus should be favoured for treatment.

Keywords: Tennis elbow, Corticosteroid, Platelet Rich Plasma, VAS Score, MAYO Elbow Score

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INTRODUCTION

Lateral elbow epicondylar tendinosis or 'tennis elbow' (TE) is a condition occurring at the common extensor tendon that takes origin from the lateral epicondyle. It is observed in patients whose activities require repetitive movements or strong gripping.[1,2] It causes functional impairment and pain during daily activities.[1,3] Though it has been termed tennis elbow, it is as likely to affect non-athletes as athletes.[4,5] Tennis elbow has numerous aetiologies including repetitive wrist turning or hand gripping, tool usages, shaking hands and twisting movements that may exceed tissue capacities and lead to micro-trauma. Over use of the wrist extensor musculature can lead to injury and enthesopathy, usually around the lateral epicondyle; this is a common cause of the condition.[6,7]

There are many treatment options for tennis elbow.[8,9] Treatment is initially conservative, including rest, anti-inflammatory medications and physical therapy. Extracorporeal shockwave, injections of corticosteroids, dry needling and various surgical techniques have been incorporated in cases that do not respond to more conservative treatment.[9,10] Modalities such as local corticosteroid injection focus on suppressing inflammatory processes. A recent review article concluded that short-term outcome (6 weeks) with corticosteroid injection was better than with a 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 have been recorded, so it is not currently possible to draw a firm conclusion on the effectiveness of corticosteroid injection compared to other treatments.[11]

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 such as platelet-derived growth factor, transforming growth factor β1, basic vascular endothelial growth factor, fibroblast growth factor and epidermal growth factor, all of which have been shown to play an important role in healing.[12] Hence, we conducted a randomised control trial (RCT) to investigate the effectiveness of PRP compared with corticosteroid injection on chronic lateral epicondylitis and the possible benefit of one method over the other in the treatment of tennis elbow.

METHODS AND MATERIALS

The study was conducted in the Department of Orthopaedics, Maharajah's Institute of Medical Sciences (MIMS), Vizianagaram, Andhra Pradesh, India over a period of 23 months from January 2019 to December 2020. Subjects were recruited from patients presenting in the orthopedics outpatient department with a primary diagnosis of lateral epicondylitis (tennis elbow). Written informed consent was obtained and a formal diagnosis of lateral epicondylitis was made on clinical grounds. We conducted a randomised control trial (parallel study design) from a potential sample size of 85 consecutively reporting subjects. Subjects were assessed for eligibility, and 25 subjects were excluded. Inclusion criteria were: patients with pain and tenderness over the lateral epicondylar region; a positive Cozen's test with the duration of symptoms longer than three months; pain severity with minimum score of 5 (based on the 10 scale Visual Analogue Scale); aged between 18 and 60 years of age; and who provided informed consent. Exclusion criteria was a history of trauma or surgery to the concerned elbow; cervical radiculopathy; and those who were not willing to participate in study.

A total of 60 patients passed the inclusion criteria and provided informed consent. These study subjects were systematically and randomly allocated (by a computer using block randomization) into two groups of n=30 each, Group A (corticosteroid) and Group B (PRP). The sample (n=60) was analysed using a standard formula, considering 95% confidence level, z value 1.96, and margin of error 0.05.

Structured study instruments (case reporting forms) were developed and used to generate data. Assessment was carried out using a standard elbow examination system: the Modified Mayo Clinic

Performance Index for the Elbow (MAYO) and Visual Analogue Scale (VAS) for pain. One assessor filled out the questionnaire of MAYO scores, recorded VAS scores and conducted the statistical analysis. They were blinded to which group the patient they were recording had been assigned. The procedure was carried out under aseptic precautions. 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 tender area around the epicondyle.

For the PRP patients (Group B), 3ml of the extracted platelet rich plasma was injected into the most tender area around the epicondyle with a standard 20-gauge needle. The PRP process was conducted by drawing 10ml of blood from the patient, which was introduced into two EDTA containing tubes with 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. The second spin was at 3500 rpm for 10 min for further concentration of platelets. The supernatant platelet-poor plasma was discarded and 1ml of concentrated platelets was obtained. The platelet counts for PRP and unprocessed blood were assessed. The PRP showed mean concentration of 3–4× platelet compared with whole blood.[77] The PRP injection was administered with the patient in the sitting position, arm at the patient's side, 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 use of the arm for at least 24 hrs. An arm sling was provided. Patients were called for follow-up after 1, 2 and 6 months. They were assessed through the same examination system, with scores recorded for performance (MAYO) and pain (VAS). Interpretation and analysis of data was carried out using SPSS-version 16.0 (SPSS Inc) software for data analysis.

RESULTS

Out of the 60 subjects evaluated, 25 were male (42%), and 35 were female (58%) (Table 1); 44 (74%) had pain in the right elbow (n=44, 74%) and 16 (26%) in the left elbow. The age distribution of the group was 35% (n=21) 18–40, 65% (n=39) 41–60 years, with a mean age of 42.5 years. This age distribution is similar to results recorded by Omar et al[18], as is the higher ratio of women to men (58:42). The higher percentage (74%) of symptoms presenting in the right elbow than the left (26%) is also consistent with other studies[19] in which 63% patients had lateral epicondylitis on the right side; in most cases, this was the patient's dominant side[19]. The pre-procedural difference between the two groups for the VAS score and MAYO scores was calculated and was not statistically significant (p=0.117 and 0.085 respectively).

The VAS 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 scores mean ± SD were compared using the t-test of independent means at the three time frames. The p-value was >0.05 in the 1 month and 2 month follow up. Thus, PRP offered no superior benefit over steroids in short term follow up. The p-value was statistically significant however when the mean ± SD of the VAS score was compared at 6 months follow up, which showed that PRP offered better analgesia as compared to steroid over the long term (Table 3).

The mean ± SD of the MAYO core was also 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 and thus not statistically significant. However, at t=6 months p<0.05, which is statistically significant. Hence PRP was again shown to be a better mode of treatment for lateral epicondylitis on long term follow up when compared to steroids with regard to elbow function (Table 4).

Some complications associated with the intervention were observed 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. Two patients had local skin atrophy, both in the steroid group. Patients from neither group reported elbow stiffness, infection, reflex sympathetic dystrophy, post-injection flare, facial flushing, neurovascular damage or tendon rupture or other untoward complications (Table 5).

Table 1 Demographic distribution of the study group (age, sex, arm side)

	No of subjects	Percentage (%)
Age (18-40yrs)	21	35
Age (41-60yrs)	39	65
Sex (Male)	25	42
Sex (Female)	35	58
Side (Right elbow)	44	74
Side (Left eblow)	16	26

Table 2 Pre-Procedure VAS Score and Elbow Score

	Group A (Steroid) (Mean ± SD)	Group B(PRP) (Mean ± SD)	p value
Preprocedure VAS score	7.86 ± 1.22	8.36 ± 1.09	0.117 NS
Preprocedure Elbow score	64.88 ± 6.95	61.75 ± 7.01	0.085 NS

Table 3 Comparison of the Pain Score (VAS) in the Study Group

	Group A (Steroid) (Mean ± SD)	Group B (PRP) (Mean ± SD)	p value
1 month FU t=1	2.36 ± 1.18	2.46± 0.93 7	0.608NS
2 months FU t=2	1.33 ± 0.80	1.56± 0.935	0.535NS
6 months FU t=6	4.60 ± 1.54	.76± 1.63	<0.001HS

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

Table 4 Comparison of MAYO Elbow scores in the study group

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

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

Table 5 Complications in the study groups

	Steroid	PRP
Local exacerbation	3	8
Skin	2	0
Infection	0	0

DISCUSSION

Lateral epicondylar tendinosis is a common problem with many possible treatments. Corticosteroid injections have been used extensively for this problem, but studies show that there is conflicting evidence regarding their efficacy.[13-15] More than 30 years ago, Jobe and Ciccotti (1994)[16] concluded that superficial injection of corticosteroid may result in subcutaneous atrophy and that intratendinous injection may lead to permanent adverse changes within the ultrastructure of the tendon. Despite these issues, corticosteroid is still widely used.[16,17]

In this study, the baseline pain and function scores of the two groups, i.e. corticosteroid and PRP injection, were comparable with regard to VAS score and MAYO score before intervention (7.86±1.22 and 8.36±1.09 respectively with p=0.117 between the two groups). Similar observations have been made by Omar et a (2012),[18] Peerbooms et al (2010)[19] and Mishra et al (2006).[20]

In terms of efficacy of treatment, Corticosteroid or PRP injection showed similar responses in the short-term follow up. At the 1 month and 2 month follow up, there was no statistically significant difference (p=0.608) between the two groups, which is similar to observations made by Omar et al (2012).[18] At first and second follow up visit, both groups had improved significantly relative to the baseline scores but there was insignificant difference in the improved outcome measures[15] relative to which treatment they had been assigned. Comparable observations made in other studies also showed good short-term response for pain resolution from both treatments.[19,20]

When pain was assessed after 6 months of intervention, however, the difference in the mean scores between the two groups was statistically highly significant (steroid group 4.60±1.54, PRP group 0.76±1.63, p-value <0.001). Similar results were obtained by Mishra et al, who concluded that treatment with buffered PRP offered better long-term results when compared to corticosteroids.[20]

The study was limited by a small sample size selected from a geographically limited population. Further studies with larger study groups and multicentric studies are needed to validate the results.

CONCLUSION

This study describes the comparison of an autologous platelet concentrate (PRP) with commonly used corticosteroid injection as a main therapy for lateral epicondylitis in patients who failed to respond to more conservative treatment. It suggests that a single injection of concentrated autologous platelets improves pain and function significantly more than corticosteroid injection. These improvements were profound and sustained over longer periods of time as compared to corticosteroid injection, suggesting the PRP injection should be favoured in the treatment of this condition.

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