



# COMPARISON BETWEEN ULTRASOUND THERAPY VERSUS AUTOLOGOUS BLOOD INJECTION IN THE MANAGEMENT OF PAIN AND IMPROVING FUNCTIONAL OUTCOME IN PATIENTS SUFFERING FROM CHRONIC LATERAL EPICONDYLITIS: A RANDOMIZED CONTROLLED TRIAL

## Orthopedics

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## ABSTRACT

**Background** Tendon pain is common in professional athletes as well as in sedentary people. It occurs in 30% -50% of all sports related injuries. Incidence of injury has been reported in various forms. For instance, in club gymnastics injury rates vary between 2 to 4 and 39.9 per 100 school children per year. It has been found to occur in approximately 1-3% of people in studied populations. The peak incidence is in the early fifth decade and a nearly equal gender incidence is seen. Tennis elbow is seen commonly associated with obesity, smoking and physical loading during activity as well as playing tennis. Various conservative treatments are available but none of them proved to be superior in treating the condition. This study was conducted to check the efficacy of Autologous blood injection as a new treatment modality.

**Materials And Methods** A Randomized controlled trial was conducted in the Department of Physical Medicine and Rehabilitation (PMR), Regional Institute of Medical Sciences (RIMS), Imphal, Manipur for a duration of Two years (june 2018 to july 2020). All patients suffering from chronic lateral epicondylitis attending department of Physical Medicine & Rehabilitation, Regional Institute of Medical Sciences, Imphal during the study period.

**Results** In this study, the mean improvement of VAS and PRTEE score were found to be statistically significant ( $p < 0.05$ ) in both the ABI and ultrasound therapy group. At 2 weeks and 3 months follow-up ultrasound therapy group shows more improvement compared to the group received ABI. But at 6 months follow-up ABI group shows more improvement of VAS and PRTEE score compared to the ultrasound therapy group and which was statistically significant.

**Conclusion** Single dose of autologous blood injection (ABI) is superior to ultrasound therapy in the treatment of Chronic lateral epicondylitis.

## KEYWORDS

### INTRODUCTION

Lateral epicondylitis also known as the tennis elbow is a term used to describe myriad of symptoms around the lateral aspect of the elbow which occurs more frequently in nonathletes than athletes.<sup>1</sup> The disorder arises as a result of repetitive movements of the involved muscles particularly in the working age group. The disease imparts significant disability in terms of the quantity and quality of work done. Tennis elbow may also cause significant weakness of grip strength particularly with the elbow in extension.<sup>2</sup>

The pathology of lateral epicondylitis results from overuse of the extensor muscles leading to degenerative pathology of the involved tendons.<sup>3</sup> Although it is known as a tendonitis, histopathologic studies have shown that it is associated with few inflammatory cells but more associated with hypertrophy of fibroblasts, abundant disorganized collagen, hyperplasia of vascular elements, apoptosis and extracellular matrix breakdown.<sup>4</sup>

The diagnosis of tennis elbow is usually made clinically by localizing discomfort at the origin of the extensor carpi radialis brevis. Tenderness is present over the lateral epicondyle approximately 5 mm distal and anterior to the midpoint of the lateral epicondyle. Pain usually is exacerbated by dorsiflexion of wrist against resistance and forearm supination and on grasping objects.

Numerous different methods have been proposed to treat tendinopathy, such as eccentric training, the injection of corticosteroids and sclerosants, prolotherapy, ultrasound therapy, extracorporeal shockwave therapy and glyceryl trinitrate patches.<sup>5</sup> Corticosteroid injection has been shown to provide short term relief but relapse rates are high. Recent literature suggests that corticosteroid injections may actually have deleterious effects after their short-term pain relief.<sup>6</sup> Unfortunately, few of these treatments have shown consistent effectiveness and the evidence for most treatment options is sparse. The lack of prospective or randomized studies comparing treatment options makes evaluating their effectiveness difficult. Currently, eccentric training is the first choice of treatment of most practitioners, although the methodological quality of the studies suggesting efficacy has recently been questioned.<sup>7,8</sup>

Autologous blood injection has emerged as one of the acceptable modalities of treatment. Long term studies over a larger group of patients are however lacking. Autologous blood injection was found to be one of the modalities for treatment of lateral epicondylitis. Being cheap, available and easy method of treatment, it should be considered as a treatment modality before opting for the surgery.<sup>9</sup>

Injection of autologous blood has been reported for the treatment of tendinopathy. It is hypothesized that transforming growth factor- $\beta$  and basic fibroblast growth factor carried in the blood will act as humoral mediators to induce the healing cascade. Musculoskeletal Ultrasound can document the pathology prior to the injection and accurately identify the site for injection and there after monitor tendon healing.<sup>10</sup>

### MATERIALS AND METHODS

**Study Design:** Randomized controlled trial

**Setting:** Department of Physical Medicine and Rehabilitation (PMR), Regional Institute of Medical Sciences (RIMS), Imphal, Manipur.

**Study Period:** Two years (june 2018 to July 2020)

**Study Population:** All patients suffering from chronic lateral epicondylitis attending department of Physical Medicine & Rehabilitation, Regional Institute of Medical Sciences, Imphal during the study period.

### INFORMED CONSENT AND ETHICS APPROVAL

All the participants were informed about the nature and risks involved in the study and those who agree to participate were asked to sign the informed consent form. Participants were assured that they can withdraw from the study at any time. The approval of the Research Ethics Board, RIMS, Imphal also was taken before starting the study.

### SAMPLE SIZE:

A sample size of 44 in each group is calculated as follows,

$$N = (u+v)^2 \times (s_1^2 + s_2^2) / (m_1 - m_2)^2$$

where, N=sample size s=standard deviation m=mean

u=one sided % point of normal distribution, corresponding to the

desire power

$v$ =two sided % point of the normal distribution corresponding to desired significant level

#### Group A (Autologous blood):

$m_1=1.52$ ;  $s_1=1.26$  (Mean VAS score for Autologous Blood)

#### Group B (Ultrasound therapy):

$m_2=2.28$ ;  $s_2=1.28$  (Mean VAS score for ultrasound therapy)

Therefore,

$$n = (u+v)^2 \times (s_1^2 + s_2^2) / (m_1 - m_2)^2 \\ = (0.84 + 1.96)^2 \times (1.26^2 + 1.28^2) / (1.52 - 2.28)^2 \\ = 43.75 \\ = 44$$

Therefore, sample size is 88 (for both Group A & Group B combined).

Taking into consideration that, the dropout rate is 10% in this study, the total sample size is fixed at 98.

### OUTCOME MEASURES:

#### VISUAL ANALOGUE SCALE

A Visual Analogue Scale (VAS) for pain is a 10 cm horizontal line on which the patient's pain intensity is represented by a point between the extremes of "no pain at all" and "worst pain imaginable". The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in centimeters from the left hand end of the line to the point that the patient marks.

#### PATIENT RATED TENNIS ELBOW EVALUATION (PRTEE)

The PRTEE, formerly known as the Patient-Rated Forearm Evaluation Questionnaire (PRFEQ), is a 15-item questionnaire designed to measure forearm pain and disability in

patients with lateral epicondylitis. The PRTEE allows patients to rate their levels of tennis elbow pain and disability from 0 to 10, and consists of 2 subscales:

- 1) PAIN subscale (0 = no pain, 10 = worst imaginable)
  - Pain - 5 items
- 2) FUNCTION subscale (0 = no difficulty, 10 = unable to do)
  - Specific activities - 6 items
  - Usual activities - 4 items

In addition to the individual subscale scores, a total score can be computed on a scale of 100 (0 = no disability), where pain and functional problems are weighted equally. The sensitivity and specificity values associated with the PRTEE were 0.94 (95% CI=0.83–0.98) and 0.78 (95% CI=0.58–0.91) respectively.

### PROCEDURE

Patient's baseline complete hemogram and musculoskeletal ultrasonography of the affected elbow was taken before the intervention.

In group A, 2 ml of venous blood was drawn from the contralateral upper limb and blood was injected after anesthetizing the area with local injection of 2 ml of 1% lignocaine solution. The injection was administered in the operation theatre taking aseptic precautions. Patient was seated or supine with arm is on the table with wrist in prone and lateral compartment. The needle was introduced under ultrasound guidance just proximal to the lateral epicondyle and the venous blood was injected on the undersurface of the extensor carpi radialis brevis muscle.

In group B, ultrasound therapy was used over the lateral epicondyle at 3MHZ frequency at intensity of 2watt/square cm for a duration of 5 minutes for 6 sittings.

Outcome variables were measured at baseline before intervention and follow up assessment was done at 2 weeks, 3 months and 6 months.

#### Statistical Analysis

Data was collected in a pre-tested proforma. Analysis was done using

Statistical Package for the Social Sciences, SPSS 21 version. For descriptive statistics, mean and standard deviation was used. For continuous variable Student's t-test was used. Chi-square and Fisher's exact test were used for categorical variable. P-value < 0.05 was taken as statistically significant.

### RESULTS

Table 1. Baseline Characteristics Of Study Groups

| Baseline characteristics |                   | Autologous blood group (n=46) (Mean±SD) | Ultrasound therapy group (n=46) (Mean±SD) | p-value |
|--------------------------|-------------------|-----------------------------------------|-------------------------------------------|---------|
| Mean age (years)         |                   | 47.20±10.06                             | 46.20±8.79                                | 0.231   |
| Age group (years)        | 20-30             | 0                                       | 2(4.35%)                                  |         |
|                          | 31-40             | 16(34.78%)                              | 8(17.39%)                                 |         |
|                          | 41-50             | 13(28.26%)                              | 25(54.35%)                                |         |
|                          | 51-60             | 11(23.91%)                              | 7(15.22%)                                 |         |
|                          | 61-70             | 6(13.04%)                               | 4(8.70%)                                  |         |
| Sex                      | Male              | 20(43.48%)                              | 18(39.13%)                                | 0.189   |
|                          | Female            | 26(56.52%)                              | 28(60.87%)                                |         |
| Side of affection        | Right             | 30(65.22%)                              | 30(65.22%)                                | 1.000   |
|                          | Left              | 16(34.78%)                              | 16(34.78%)                                |         |
| Duration(months)         |                   | 8.47±2.31                               | 7.81±2.93                                 | 0.251   |
| Domicile                 | Rural             | 21(45.65%)                              | 28(60.87%)                                | 0.154   |
|                          | Urban             | 25(54.35%)                              | 18(39.13%)                                |         |
| Occupation               | Manual labourers  | 5(10.87%)                               | 6(13.04%)                                 |         |
|                          | Govt employees    | 3(6.52%)                                | 3(6.52%)                                  |         |
|                          | Housewife         | 27(58.67%)                              | 31(67.39%)                                |         |
|                          | Businessman       | 6(13.04%)                               | 3(6.53%)                                  |         |
|                          | Defence personnel | 3(6.53%)                                | 1(2.17%)                                  |         |
|                          | Others            | 2(4.35%)                                | 2(4.35%)                                  |         |

Table 1 shows that there is no statistical differences in the baseline characteristics between the ABI and ultrasound therapy group.

Table 2: Between And Within Group Comparison Of VAS Pain At Different Time Points

| VAS score             | Study groups           |                    | P value (Between group) |
|-----------------------|------------------------|--------------------|-------------------------|
|                       | Autologous blood (ABI) | Ultrasound therapy |                         |
| Baseline              | 6.24±0.72              | 6.18±0.63          | 0.657                   |
| 2 weeks               | 4.45±1.04              | 3.71±0.79          | <0.001                  |
| 3 months              | 3.18±1.18              | 2.71±0.84          | <0.026                  |
| 6 months              | 1.49±0.51              | 3.94±0.75          | <0.001                  |
| P value(within group) | 0.000                  | 0.000              |                         |

In this study, the mean improvement of VAS score were found to be statistically significant ( $p<0.05$ ) in both the ABI and ultrasound therapy group. At 2 weeks and 3 months follow-up ultrasound therapy group shows more improvement compared to the group received ABI. But at 6 months follow-up ABI group shows more improvement of VAS score compared to the ultrasound therapy group and which was statistically significant ( $p<0.001$ ) (Table 2).

Table3: Between And Within Group Comparison Of PRTEE Scores At Different Time Points

| PRTEE score           | Study groups           |                    | P value (Between group) |
|-----------------------|------------------------|--------------------|-------------------------|
|                       | Autologous blood (ABI) | Ultrasound therapy |                         |
| Baseline              | 40.39±14.40            | 36.20±10.03        | 0.098                   |
| 2 weeks               | 29.22±10.70            | 24.73±8.05         | 0.021                   |
| 3 months              | 18.33±5.50             | 20.65±7.79         | 0.091                   |
| 6 months              | 13.31±2.90             | 23.63±6.59         | <0.001                  |
| P value(within group) | 0.000                  | 0.000              |                         |

In this study, the mean improvement in PRTEE score were found to be statistically significant ( $p<0.05$ ) in both the autologous blood and ultrasound therapy group at 2 weeks and 6 months follow-up. But ABI group shows more improvement of PRTEE score compared to the ultrasound therapy group at 6 months follow-up (Table 3).

### DISCUSSION

Tennis elbow is a common tendinopathy that can be quite resistant to

treatment and often affect the daily activities of the people. Many conservative treatment strategies has been used in treatment of lateral epicondylitis as first line but the treatment response is often inadequate. In the present study improvement was noticed in both the groups but in the long run at 6 months ABI showed better improvement both in VAS and PRTEE scores. Hence it concludes that ABI is a safer option in the treatment of lateral epicondylitis and its efficacy needs to be further evaluated

## CONCLUSION

The present study was done to find out the efficacy of autologous blood injection in chronic lateral epicondylitis to improve pain and function. The study showed that single injection of autologous blood injection is significantly more effective in reducing pain and disability in resistant lateral epicondylitis at 6 months as compared to ultrasound therapy group and may be considered as a novel alternative for surgery in resistant cases.

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