

## **A RANDOMIZED CONTROLLED TRIAL: MISLEADING LATERAL EPICONDYLITIS**

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### **ABSTRACT**

**Objective:** To rule out the presence of inflammation around the lateral epicondyle in patients diagnosed with lateral epicondylitis and have at least 3 mo of history from onset of symptoms.

**Methods:** A total of 30 subjects were taken, both males and females between the age group 25 to 55 to observe the changes over and near the lateral epicondyle along with tendons of ECRB, ECB, Triceps, and with all insertional sites over and near the lateral epicondyle for inflammation under a guidance and supervision of a radiologist with help of MSK USG.

**Results:** No inflammatory changes were found in any of the subjects regardless of duration, age and signs and symptoms.

**Conclusion:** It can be concluded that lateral epicondylitis is a misnomer and there is no to assess the condition to rule out pathophysiology and management.

**Keywords:** Randomized controlled trial, Epicondylitis

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### **INTRODUCTION**

Lateral Epicondylitis is increasing day by day due to modified occupational needs as every job requires forward manipulation, Day-to-day activities require the same forward manipulating attitude, which creates a tight and short anterior chest wall, which causes the muscle to be short and concentrically loaded whereas the posterior is eccentrically loaded. Current conservative treatment has been proven to be ineffective as most cases appear to have persistent symptoms even after 3 to 6 mo, which indicates a medical (steroid, PRP injection) or surgical approach in which tendon repair or lengthening is carried out even after surgery most cases seem to have similar pain or reoccurrence of similar condition. So, to find the core reason behind the condition in this study we investigate the common extensor origin, Extensor Carpi Radialis Brevis, and Extensor Digitorum Communis, as pathophysiology suggest that there is the presence of inflammation on or near the ECRB, ECB, and around lateral epicondyle which is due to tendinopathy of the tendon inserting on the lateral epicondyle. A total of 30 subjects were selected who were diagnosed with lateral epicondylitis and have at least three months of persisting symptoms between ages 25-60 years [1].

LE is well known for pain, tenderness and inflammation over the common extensor origin, which includes the tendinopathy of mostly Extensor Carpi Radialis Brevis, Extensor Digitorum Communis. Pain increases due to gripping activities, flexing the wrist, resistance exercises to train the wrist, picking up heavy objects, etc. it is also known as tennis elbow; however, only 5% of tennis player seems to develop it over time. It is known by many names, such as lateral epicondylagia, lateral elbow tendinopathy, lateral elbow tendinitis, etc. It can get aggravated due to occupations mostly involving forward manipulation aggravated by professions such as plumbing, carpeting, typist, IT jobs, etc also, activities of daily living can aggravate the condition as most of the activities involve forward manipulation [2].

Lateral epicondylitis has an incidence of around a million cases per year in the United States. It is the most common disorder seen after shoulder pain. Mostly, cases between ages 40-49 seem to have more difficulty in terms of persistence of symptoms and poor prognosis with the traditional approach. The current standard for performing surgery is persistence of symptoms for at least 6 mo; also, shoulder pain can

coexist with it mostly as frozen shoulder, which can be seen before or after the onset of elbow pain similar to lateral epicondylitis [3].

So, candidates are chosen with a history of at least 3 mo or more from the onset of symptoms with no surgical, pathological, or traumatic history. All the conservative measures which have been carried out till today focuses only on reducing the inflammation due to overuse of the tendon of ECRB, ECB as it has been identified as the root cause of the condition but no diagnostic measures are generally carried out to confirm the cause which is not an evidence-based practice. The current methods of treatment will remain the same for all elbow pain regardless of duration, age, pain, and disability, which is the use of electrophysical modalities such as ultrasound and cold compression proven to reduce inflammation compiled with Stretches, Strengthening Exercises, Bracing, Myo-Fascial Release, IASTM, Dry Needling, Deep Friction Massage and avoiding activities which can aggravate the symptoms. However, the condition is most likely to reoccur as soon as the patient starts their routine, and also same symptoms can be seen in the contralateral limb after a certain period. Mostly women are more affected than men [4].

Recent studies suggest that almost all idiopathic elbow pain is seen with Scapular Dyskinesias. As per the concept of the Myo-Fascial Kinetic Chain, due to improper force transmission between the muscles, the pain can be seen anywhere in the chain, especially weakness or imbalances of Pectoralis, Deltoids, and Triceps can create similar symptoms [5-7].

### **MATERIALS AND METHODS**

A total of 30 subjects were taken both males and females between the age group 25 to 55 to observe the changes over and near the lateral epicondyle along with tendons of ECRB, ECB, Triceps, and with all insertional sites over and near the lateral epicondyle for inflammation under a guidance and supervision of a radiologist with help of MSK USG. All 30 subjects shared a common diagnosis of lateral epicondylitis and have been treated conservatively; the minimum duration of persistent symptoms of each subject is 3 mo and the maximum can be seen at 6.5 mo. Subjects were treated conservatively to date and have no history of surgical intervention. The minimum VAS score seen was 5 and if aggravated due to activities or upon palpating, it increases up to 7 to 10 on the VAS scale [8].

All subjects tried every measure to counteract the condition but it can only provide temporary relief. Patients seen between ages 25 to 55 with a minimum age is 26 and a maximum is 55. Out of all 30 subjects, the majority of them are female (18) and the remaining subjects are from the male population (12).

All subjects are taken with prior consent and information and observed for inflammation and according to the results, the conclusion has been decided.

**Study design**

An observational randomized controlled trial of 30 patients diagnosed with lateral epicondylitis at least 3 mo ago from the onset. The age group taken is 25 to 55 with no history of surgical intervention along with any pathological markers. After evaluating under the guidance and supervision of a radiologist with the help of ultrasonography the presence of inflammation over or near the lateral epicondyle is ruled out along with tendinopathy.

**Table 1: Age distribution of patients taken for observation**

Age in years	Number of patients	
	Male	Female
25-30	2	3
30-35	5	4
35-40	3	2
40-45	1	5
45-50	1	3
50-55		1
Total	12	18
	30	

The table shows the number of patients according to gender and age group. A total of 30 patients are taken to carry out the trial of which 12 are from the male population and 18 are from the female population. Between the age group 25-30, 2 males and 3 females can

be seen, in 30-35, 5 males and 4 females can be seen, in 35-40, 3 males and 2 females can be seen, in 40-45, 1 male and 5 female can be seen, in 45-50, 1 male and 3 female can be seen and in 50-55 one female patient is taken for observation.

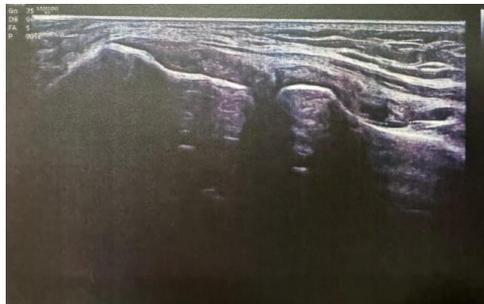


Fig. 1

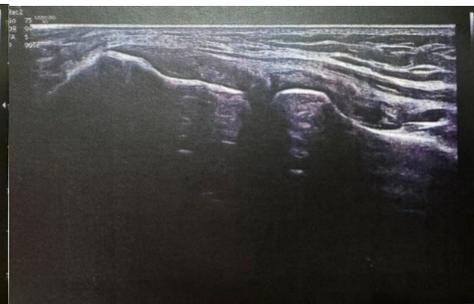


Fig. 2

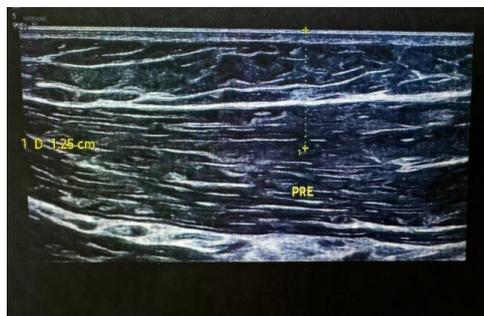


Fig. 3



Fig. 4

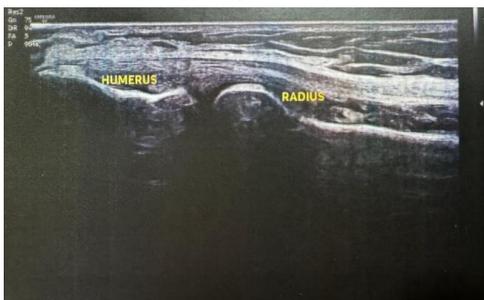


Fig. 5



Fig. 6

**Fig. 1-6: Ultrasound image report**

Table 2: VAS score of patients (n=30)

Vas	Patients	Duration
No pain (0)	0	
Mild Pain (1-3)	0	
Moderate pain (3-6)	1	3.5 mo
Severe pain (7-10)	29	4-6.5 mo

The table shows the VAS of patients with a duration of persistent symptoms. Out of all 30 subjects, 1 subject has moderate pain with a duration of 3.5 mo. The rest 29 subjects have severe pain with a duration of 4 – 6.5 mo on average.

## Methods

### Study population

Patients with lateral epicondylitis meet the needs of inclusion criteria between the ages of 25 to 55. Both males and females are taken for the trial with persisting symptoms for at least 3 mo.

### Sample size

30 patients diagnosed with lateral epicondylitis, residing in Udaipur.

### Sampling method

Random sampling method.

### Sampling technique

Random patients are taken between the age group 25-55 with a history of at least 3 mo.

### Source of data

All patients coming to Pacific Medical College and Hospital, Pacific College of Physiotherapy with a clinical diagnosis of lateral epicondylitis by an Orthopaedician also every patient meet the conditions of inclusion criteria and age group. No patient is taken with any condition mentioned in the exclusion criteria.

### Ultrasonography of right elbow joint

- No significant free fluid seen in elbow joint region.
- The visualized cortex of distal humerus and proximal radius appears normal and show no breach at present scan.
- Visualized muscles and tendons appear normal and show no tear at present scan.
- No evidence of any inflammatory changes seen in elbow joint region. There is a tiny well defined hypoechoic area approx 1.25 cms from the skin seen in proximal ECRB (extensor carpi radialis brevis).

### Inclusion criteria

- Patients diagnosed with lateral epicondylitis with at least 3 mo of persistent symptoms such as pain and tenderness over and near the lateral epicondyle.
- Age group: 25-55 y.
- Informed consent or volunteer

### Exclusion criteria

- Fracture
- Post-Surgery
- Adhesive Capsulitis
- Any Arthritis
- Any Soft Tissue Injury
- Any Congenital Or Acquired Deformities
- Progressive Disorders Including Neurological Conditions
- Open Wound And Scar
- Pregnancy

- On Medications Such As Anticoagulants, Steroid

### Limitations and recommendations

#### Limitations

- It is a clinical trial of 30 patients and the approach is limited to an opd.
- Only ultrasonography has been used as an outcome measure and through observation, the conclusion has been drawn.
- Random sampling is done without any follow-ups.
- No treatment intervention has been carried out and studied
- This clinical trial does not signify any root cause evaluation

#### Recommendations

- A bigger sample size should be taken and with a bigger approach to cover a more varied population.
- More diagnostic measures and medical professionals can be used to evaluate such as pathologists, physicians, etc to solidify the findings
- Sampling should be done before studying the subject thoroughly with post-follow-ups to increase the efficacy.
- Studies should be done by considering treatment.
- Studies should find and assess the root cause behind the condition.

## DISCUSSION

This clinical trial was carried out to rule out inflammation in lateral epicondylitis. The subjects chosen for the study are both males and females between age group 25-55 selected randomly for the clinical trial. Earlier studies based on the same criteria such as in the year 2012, Waseem M, Nuhmani S, Ram CS, Sachin Y studied lateral epicondylitis from the anatomical and pathological aspect and concluded that there is no inflammatory markers found around the lateral epicondyle but this finding was accidental as it was not the motive of the study. So, this clinical trial will add evidence to an existing conclusion by further observing the changes by specifically ruling out inflammation. Hence, the subjects are taken and selected accordingly with the specific criteria to rule out the inflammation which adds more specificity and evidence.

All the subjects were selected according to inclusion criteria, simultaneously excluding the conditions mentioned in the exclusion criteria. All the subjects were given information and prior consent has been taken to provide all the information to the before investigating the condition. After which a thorough examination is done by using ultrasonography, the machine is operated by a radiologist, and with proper review and observation, a report is produced by the radiologist in the outpatient department of Pacific Medical College and Hospital, Udaipur (313001), Rajasthan.

## CONCLUSION

After observing all the patients, it can be concluded that there have been no signs of inflammation and free fluid found over or near the lateral epicondyle along with no tendinopathy or tendinitis can be seen in the tendons of Extensor Carpi Radialis Brevis, Extensor Digitorum Communis, and Triceps Brachii. Although fascial irregularities can be seen clearly with hypoechoic areas, which are

trigger points and upon palpating the pain can be found in the exact area. Also, age-related changes can be seen in old aged patients especially women who have more presence of osteophytes due to irregularities in calcium absorption after menopause is very common. Other than that there is no signs are present which indicates the presence of inflammation.

Hence, it can be concluded that lateral epicondylitis is a misnomer and the conservative treatment approach, which focuses on reducing the inflammation at the pain site, is obsolete and root cause diagnosis must be done by focusing on the global issues as per the concept of kinetic fascial chains among which specifically deep arm front line and superficial back arm line or any other method or concept [9].

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Nil

#### AUTHORS CONTRIBUTIONS

All the authors have contributed equally

#### CONFLICTS OF INTERESTS

Declared none

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