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**Sourabh Chachan**  
MBBS, MS (Ortho), MRCS  
(Edin.), Department of  
Orthopaedics, Changi General  
Hospital, Singapore

**Biswajit Sahu**  
MBBS, MS (Ortho), Associate  
Professor, Department of  
Orthopaedics, VSS Medical  
College, Burla, Odisha, India

*Original Article*

## A randomized controlled clinical trial evaluating the role of intra-lesional steroids in the management of tennis elbow

**Sourabh Chachan and Biswajit Sahu**

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### **Abstract**

Although intra-lesional steroids are widely used in the management of tennis elbow, some recent reports have doubted their usefulness. A prospective double-blinded randomized controlled clinical trial was conducted to evaluate the usefulness of intra-lesional steroid injections in tennis elbow. The study included 78 cases with a mean age of 39.8 years, who were divided into two randomized groups A (experimental) and B (control). Group A received one intra-lesional injection of 10mg triamcinolone acetate (40 mg/ml) mixed with 0.75 ml of 2% plain lignocaine using peppering injection technique, followed by stretching exercises, whereas group B received only stretching exercises. Follow-up was done for 4 months using fortnightly patient-rated tennis elbow evaluation score (PRTEE). Statistical analysis was done using Student t-test. Average PRTEE score in group A and B at beginning were 78 and 80, respectively. After 4 months, average PRTEE score in group A was 24 and in group B was 25 (p value=0.97, insignificant). Nearly 74% group A patients reported mild to severe intensity pain in immediate post-injection period, which subsided in few days with or without medication. It was concluded that the use of intra-lesional injections does not seem to significantly affect the outcome in tennis elbow.

**Keywords:** Tennis elbow, triamcinolone acetate, PRTEE, stretching exercises, peppering injection technique

### **Introduction**

Lateral epicondylitis or tennis elbow is a painful condition of the elbow which has commonly been attributed to the inflammation and degeneration of the extensor carpi radialis brevis origin on the lateral epicondyle of humerus [1-3]. Despite being commonly called as tennis elbow, this condition is more common in general population and is mostly associated with work-related activities [2, 3]. The most common symptom is pain which is aggravated by gripping, heavy lifting, or simple tasks of daily living [2]. Although the disease is known since long time but no definitive guidelines are available for the treatment of this significantly painful and incapacitating condition [4, 5]. The various modalities of treatment advocated are rest and immobilization, anti-inflammatory medications, intra-lesional steroid injections, manipulations, physiotherapy regimes and surgery [2-6]. The use of intra-lesional steroid injections by both general practitioners and orthopedic surgeons is very common [7-11]. Advocates of steroids cite their usefulness as anti-inflammatory agents and their ability to provide relief from local symptoms of pain and discomfort [7-11]. Few recent reports have stated that they do not work any better than placebos [12-14]. With the aim to further clarify the usefulness of intra-lesional steroid injections in treating tennis elbow, this study was conducted.

### **Materials and methods**

It was a randomized controlled clinical trial study. Subjects were selected from among the patients who attended Orthopedics clinic of a tertiary care center between 1<sup>st</sup> February 2014 and 31<sup>st</sup> July 2016. Diagnosis was made on the basis of history and clinical examination.

**Correspondence**  
**Sourabh Chachan**  
MBBS, MS (ortho), MRCS  
(Edin.), Department of  
Orthopaedics, Changi General  
Hospital, Singapore

Following inclusion and exclusion criteria were used.

#### Inclusion criteria

- 1) Duration of symptoms equal to or less than 4 weeks.
- 2) No history of any such illness episode in the past.
- 3) No history of treatment for the same, except self-imposed rest to the affected side.
- 4) No history of direct or indirect trauma to the painful site.
- 5) No history of any neurological or vascular disease.
- 6) No history of any cervical spine problems.
- 7) Normal spine, shoulder, elbow and wrist examination except for the specific signs of tennis elbow like Thomson test, Cozen test, Mill's test.

#### Exclusion criteria

- 1) Lack of full elbow extension or forearm supination due to any reason.
- 2) Patients on steroid medications for any medical or surgical condition.
- 3) History of steroids medication within the past 1 year.
- 4) Co-morbid local and systemic medical and surgical conditions precluding the administration of intra-lesional steroids or stretching exercises.

Two groups were created A (experimental) and B (control). The patients were informed about the study purpose and randomized. For randomization, the patients first seen on Monday, Wednesday and Friday were added to group A and while those first seen on Tuesday, Thursday and Saturday were added to group B. Group A patients received 10mg triamcinolone acetate (40mg/ml) with 0.75 ml 2% plain lignocaine. The 25G needle was used for the injection. Following injection, patients were strictly advised against any heavy activity and advised to rest the extremity for one week with the instruction to follow-up after one week when stretching exercises were begun. Exercise was performed for a total of ten times twice daily. The patients in group B performed only stretching exercises from the beginning. Patients in both the groups were advised to lift object with forearms in supination and avoidance of wringing and rotatory movements of hand and avoiding tasks which involve forceful gripping. To maintain consistency, all the intra-lesional injections were given by the same person and all the subjects were evaluated for the technique if stretching exercises at every follow-up visit.

Technique of intra-lesional injection- It was done in the following step-wise manner [Fig. 1a, 1b, 1c].

- 1) Patient sits with elbow flexed to 90 degrees and forearm in neutral position.[Fig. 1a]
- 2) Through palpation, most tender point in elbow is identified which is generally, the anterior facet of lateral epicondyle.[Fig. 1b]
- 3) After sterile preparation of skin, needle is inserted in line with elbow crease perpendicular to the facet to touch bone and then withdrawn slightly. [Fig. 1c]
- 4) Solution was injected into tendon origin in the peppered manner.

Technique of stretching exercise- It was performed in the following step-wise manner.

Stretching exercise number 1 [Fig. 2a, 2b]

- 1) Patient sits on a stool with shoulder forward flexed to 90 degrees, elbow in full extension, forearm in full supination, wrist maximally dorsi-flexed and all fingers in full extension at metacarpo-phalangeal, proximal and distal inter-phalangeal joints.[Fig. 2a]

- 2) The patient tries to further dorsi-flex the wrist passively by applying force to fingers through the other hand.[Fig. 2b]
- 3) The steps are repeated ten times.

#### Stretching exercise number 2 [Fig. 3a, 3b]-

- 1) Patient sits on a stool with shoulder forward flexed to 90 degrees, elbow in full extension, forearm in full pronation, wrist maximally palmar-flexed and all fingers in full extension at metacarpo-phalangeal, proximal and distal inter-phalangeal joints.[Fig. 3a]
- 2) The patient tries to further palmar-flex the wrist passively by applying force to fingers through the other hand.[Fig. 3b]
- 3) The steps are repeated ten times.

Patients were followed-up at fortnightly intervals for a total period of 4 months. Patient evaluation was done using Patient-rated tennis elbow evaluation score (PRTEE) [15]. The scores were recorded at the beginning of treatment and then at subsequent fortnightly follow-ups, till the end of study. The data was analyzed using student t-test.

Table 1: Statistical Data

Time (Months)	Group A (Experimental) Average Prtee Scores	Group B (Control) Average Prtee Scores
0	78	80
0.5	73	74
1	57	66
1.5	49	57
2	41	49
2.5	35	43
3	27	38
3.5	25	30
4	24	25
AVERAGE	45.44	51.33
T-TEST p value	0.54	

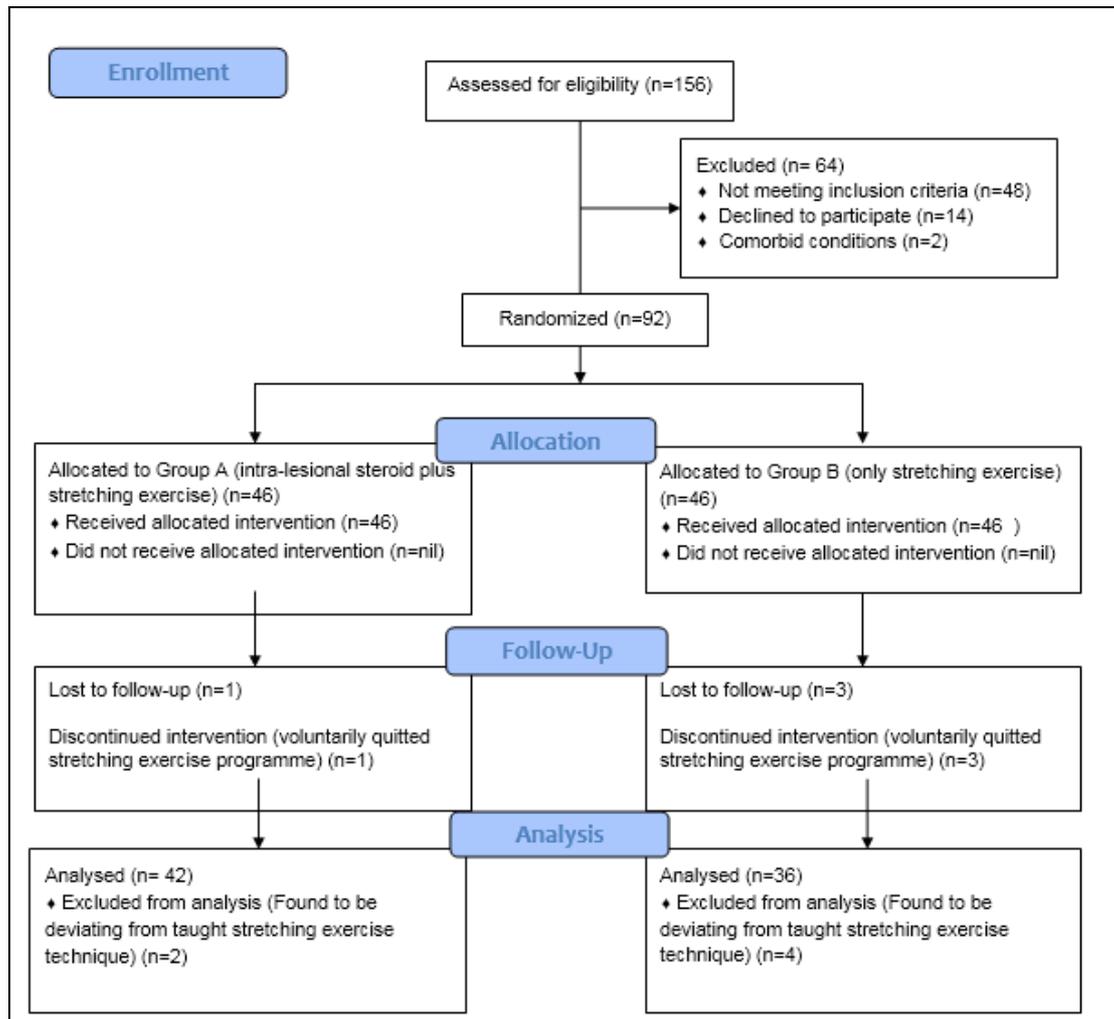
#### Results

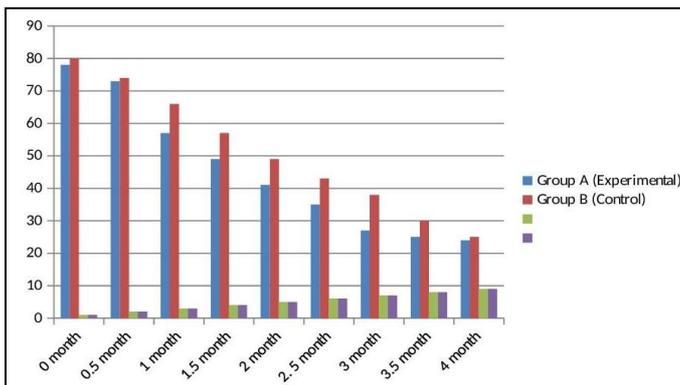
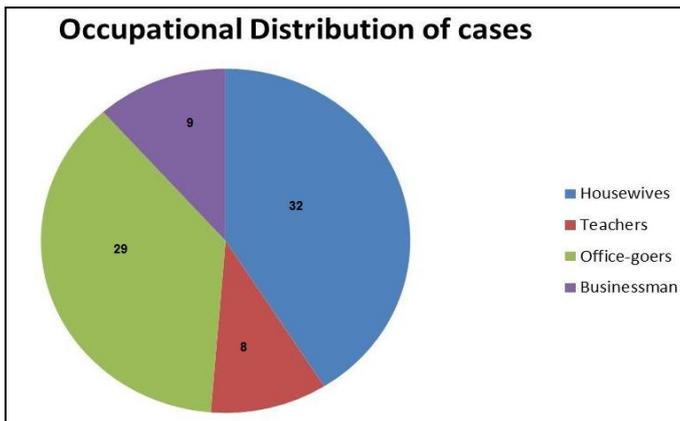
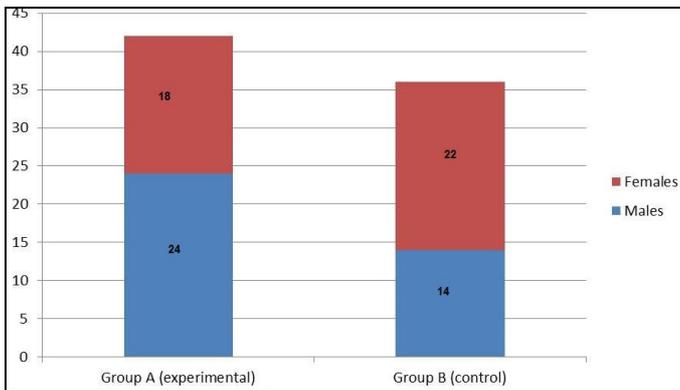
On the basis of above said criteria, a total of 92 patients were included in this study, out of which 48 were males and 44 were females. All of them were non-sports person. All belong to the age group of 23-48 years, with the average age of 38.6 years. Out of the total patients, 4 were lost to follow-up, 4 patients voluntarily quitted stretching exercises and 6 were found to be deviating from the taught technique of stretching exercises and so were excluded from the final analysis. Final analysis included 78 patients, 38 males and 40 females with a mean age of 39.8 years (range=23-48 years) [Fig. 4]. In the final analysis, Group A had 42 (male-24, female-18) and B had 36 (male-14, female- 22) patients [Fig. 4]. Out of all the females 80% were housewives and rests were teachers [Fig. 5]. Among males nearly 76% were office goers and rest had their own businesses [Fig. 5]. None of the subjects were involved in any kind of heavy weight lifting or heavy manual work. At the end of study, there was no significant difference in the degree of functional improvement and relief of symptoms of pain and muscle spasm between the two groups. Both the genders responded equally to both the modalities of treatment with equal treatment rates in both the groups. As shown in Table no. 1, average PRTEE score in group A decreased from 78 in the beginning to 24 at the end of 4 months, while in group B it decreased from 80 to 25 after 4 months [Fig. 6]. The whole

data was analyzed using student paired t-test and p value came out to be 0.54, which is insignificant. 31 out of 42 (74%) group A patients reported mild to severe local pain in the

immediate post-injection period. The pain subsided within a few days, with some patients requiring mild analgesics for the same. No other complaints were seen in any of the group.

**Consort Flow Diagram of the study**





**Discussion**

Tennis elbow most commonly occurs in the 35-50 year age group and is more common in men than women [6]. It is a highly incapacitating musculoskeletal condition affecting people from all spheres of life. The disease although named as tennis elbow, is not limited to tennis players, but also seen in common population being mostly associated with work-related activities. The inflammation most commonly involves the dominant side which is right in most of the cases [6]. The incidence is high and ever increasing and the affection is incapacitating, adversely decreasing functional ability of the person and sometimes leading to complete cessation of work activities. The treatment is still debatable with different schools of thought advocating different approaches. Rest and immobilization although seems to be the most critical part of treatment process [1, 3, 4]. We found these modalities as impractical due to two reasons. One, most of the patients could not afford to take leave from jobs and secondly, the involvement of dominant side. The second most effective treatment modality is physiotherapy in the form of stretching exercises [16, 17]. Since the condition arises due to degeneration of tendinous origin of extensor carpi radialis brevis muscle, the

use of stretching exercises seems to be the right approach. But physiotherapy regimes have the problem of poor patient compliance. Intra-lesional steroids are commonly used for providing pain relief and are also assumed to decrease local inflammation through their anti-inflammatory properties [7-11]. Many studies have compared the intra-lesional steroid injections against intra-lesional placebo (saline) injections, and have reported no difference between the two groups [12-14]. But one major drawback with these studies was the use of same peppering technique of injection in both experimental and control groups. Various recent reports have stated the usefulness of peppering injection technique in treating tennis elbow [18], whereas some studies state that peppering injection technique may be harmful [18, 19]. So the peppering injection technique used in such control studies may act as a confounding factor and affect the final outcomes. This study was designed to omit the confounding factor of peppering technique and subsequently provide a fairer evaluation of steroid usefulness. At the end of treatment, evaluation scores differed by only one point in control and experimental group (Group A=24, Group B=25, p value=0.54, insignificant). Along with it 31 cases in group A i.e. who received steroid injections, also complaint of post injection pain which was mild to severe in intensity. Although there are few reports of tendon rupture following steroid injections but we did not encounter any such complication in this study [20]. In this study, steroids were not found to significantly affect the course of this disease. This study along with various other ones, has questioned the rationale behind steroid use in tennis elbow [12-14, 21-23]. Intra-lesional steroid injections not only cause post injection pains, but also result in higher health expenditures. The high recurrence rates, general delay in recovery, and poor overall performance with corticosteroid injections should be taken under consideration by both patients and their doctors in the management of tennis elbow [4]. Moreover, recent systematic reviews report that poor quality of methods is a problem with much of the published research. This study has the added advantage of avoiding the confounding factor arising due to use of peppering injection technique in both experimental and control groups.

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