Original Article

“A study of efficacy with local methyl prednisolone acetate injection versus autologous blood injection in the treatment of lateral epicondylitis"

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ABSTRACT

Background & Objectives: Lateral epicondylitis, is a common problem encountered in the orthopaedic practice. It is a common practice to give local corticosteroid infiltration for tennis elbow. Histopathological reports have shown that lateral epicondylitis is not an inflammatory process but a degenerative condition termed ‘tendinosis’. Beneficial effects of local corticosteroid infiltration have sound lack of scientific rationale, since surgical specimens show lack of any inflammatory process. In recent studies no statistically significant or clinically relevant results in favor of corticosteroid injections were found. Recently an injection of “autologous blood injection” has been reported to be effective for both intermediate and long term outcomes for the treatment of lateral epicondylitis. It is hypothesized that blood contains platelet derived growth factor induce fibroblastic mitosis and chemotactic polypeptides such as transforming growth factor cause fibroblasts to migrate and specialize and have been found to induce healing cascade. The objective of the study is to compare the functional outcome of local Methyl prednisolone acetate injection versus Autologous Blood injection in lateral epicondylitis. Materials and Methods: A prospective, randomized study was done in R L Jalappa Genaeral Hospital. 60 patients were included in the study. 30 patients received 2 milliliter autologous blood and 30 patients received 2 milliliters local corticosteroid (Methyl prednisolone acetate 80 mg) at the lateral epicondyle. Outcome is measured using ‘Pain score’. Student t test is applied to calculate the significance of results. Results: Follow-up done for total 6 months divided in to intervals at 2week,2 month and 6 month. At 2nd week the corticosteroid injection group showed a statistically significant decrease in pain compared to autologous blood injection group. At 2nd month and 6 months follow up autologous blood injection group showed statistically significant decrease in pain compared to corticosteroid injection group. At the end of 6 months 46.66% patients in Corticosteroid injection group and 90% patients in autologous blood injection group were completely relieved of pain. In Corticosteroid injection group till 2nd month there was significant improvement with 63.3% of patients completely relieved of pain. Many of these patients reported recurrences at 6th month follow up. The rate of recurrence was 36.8% at the end of 6 months. In autologous blood injection group at 2nd month follow up, 16.66% of patients were completely free of pain. At the end of 6 months follow up, 90% of patients were completely free of pain. There was no recurrence. Interpretation & Conclusion Autologous blood injection technique for lateral epicondylitis offers a better treatment with least side effects, cost effective and with minimum recurrence rate.

1. Introduction

Lateral epicondylitis, or tennis elbow, is a commonly encountered problem in orthopedic practice. It has been found to be the second most frequently diagnosed musculoskeletal disorder in the neck and upper extremity in aprimary care setting.

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frequent than the medial. Its name “Tennis elbow” is a misnomer because it occurs more commonly in non athletes than in tennis players. The most widely held theory is that there are macroscopic or microscopic tears in the common tendon as described by Cyriax4

Much controversy has been there over the pathophysiology and there is not enough scientific evidence to favour any particular type of treatment for acute lateral epicondylitis. Currently degeneration of the origin of the extensor carpi radialis brevis (ECRB), repeated micro trauma and incomplete healing response has been accepted as the cause of lateral epicondylitis by most of the researchers.

Histopathological reports have shown that lateral epicondylitis is not an inflammatory process but a degenerative condition termed ‘tendinosis’.5,6. There are numerous treatment modalities for lateral epicondylitis both conservative and operative. Most conservative modalities such as local corticosteroid injection have focused on suppressing the inflammatory process that does not actually exist. A recent review article concluded that for short term outcomes (6 weeks), statistically significant and clinically relevant differences were found on pain and global improvement with corticosteroid injection compared to placebo, local anaesthetic, or other conservative treatments.13. For intermediate (6 weeks to 6 months) and long term outcomes (more than 6 months), no statistically significant or clinically relevant results in favour of corticosteroid injections were found. So it is not possible to draw a firm conclusion on the effectiveness of corticosteroid injection.13.

Recently an injection of autologous blood has been reported to be effective for both intermediate and long term outcomes for the treatment of lateral epicondylitis. There was a significant decrease in pain.5. It is hypothesized that mitogens such as platelet derived growth factor induce fibroblastic mitosis and chemotactic polypeptides such as transforming growth factor cause fibroblasts to migrate and specialize and have been found to cause angiogenesis. A specific humoral mediator may promote the healing cascade in the treatment of tendinosis as well. These growth factors trigger stem cell recruitment, increase local vascularity and directly stimulate the production of collagen by tendon sheath fibroblasts.5

Autologous blood was selected as the medium for injection because (1) its application is minimally traumatic, (2) it has a reduced risk for immune-mediated rejection, devoid of potential complications such as hypoglycemia, skin atrophy, tendon tears associated with corticosteroid injection (3) it is simple to acquire and prepare, easy to carry out as outpatient procedure and (4) it is inexpensive.5

There are very few studies done to evaluate injection of autologous blood for lateral epicondylitis as treatment modality. Hence it is evaluated by comparing with the corticosteroid injection which is a commonly practiced conservative treatment modality.5

The purpose of this dissertation is to evaluate the efficacy and role of autologous blood injection at lateral epicondylitis by comparing with local corticosteroid injection (methyl prednisolone acetate).

Patients and Methods

Our study population has a high proportion of people involved in manual labour. There is no current published data on the prevalence of lateral epicondylitis in the region where the study was conducted. Age > 18 years and a diagnosis of lateral epicondylitis were the inclusion criteria. The exclusion criteria were: 1) patients receiving steroid injections in the three months prior to study treatment; 2) history of substantial trauma; 3) previous surgery for lateral epicondylitis; 4) presence of other causes of elbow pain such as osteochondritis dessicans of capitellum, epiphyseal plate injuries, lateral compartment arthrosis, varus instability, radial head arthrits, posterior interosseous nerve syndrome, cervical disc syndrome, synovitis of radiohumeral joint, cervical radiculopathy, fibromyalgia, osteoarthritis of elbow, or carpal tunnel syndrome. Each patient was assessed by history and clinical examination. In some cases radiological and imaging investigations were carried out to confirm the diagnosis and to identify any exclusion criteria. Patients attending outpatient department were included after a diagnosis of lateral epicondylitis was established. This included interview and clinical examination comprising testing for tenderness over the lateral epicondyle or just distal to it, a positive Cozen’s test and Mill’s manoeuvre. In 12 cases diagnosis was confirmed with radiography and in 10 cases by USG, after radiographs were inconclusive. Patients were allotted sequentially into two parallel groups, A and B, of 30 cases each. Equal randomisation (1:1 allocation ratio) was undertaken according to a computer-generated randomisation table. Procedure. Group A was designated to receive an injection with 2 ml of local methyl prednisolone acetate (80 mg), at the lateral epicondyle according to the technique described below. Group B was designated to receive an injection with 2ml of autologous blood according to the same technique.

Fig 1 Autologous blood injection at lateral epicondyle
Briefly, the technique is as follows (Fig. 1). With the patient in supine or sitting posture the elbow is flexed to 90° with the palm facing down. The anatomical bony landmarks were identified. Under aseptic precautions the needle is introduced proximal to the lateral epicondyle along the supracondylar ridge, and gently advanced to the undersurface of the extensor carpi radialis brevis while infiltrating. A small adhesive sterile dressing is applied. Patients are advised to rest the upper limb for three days, with no restriction of activity after that.

**Outcome evaluation:** Outcome in terms of pain relief was assessed using a visual analogue scale (VAS). The VAS comprised a 10 cm line marked at one end with ‘no pain’ and at other end with ‘worst pain ever’. The participant is asked to indicate where on the line he or she rates the pain on the day of presentation.

The VAS score is assessed by visit to the clinic pre-injection, and at 2nd weeks, 2nd month and at the six-month final follow-up.

**Statistical analysis:** The Student t test (non-parametric test) was used to compare outcome regarding pain between the two groups. The chi-squared test was used to compare categorical variables between the groups. A p-value < 0.05 was considered to indicate statistical significance.

**Discussion and Results**

Tennis Elbow is a common problem encountered in Orthopaedic practice and general Practice. Majority of the treatment modalities used for its management lack scientific rationale. The role of local steroid is debatable. Recently an injection of autologous blood has been reported to be effective for both intermediate and long term outcomes for the treatment of lateral epicondylitis. There was a significant decrease in pain. It is hypothesized that mitogens such as platelet derived growth factor induce fibroblastic mitosis and chemotactic polypeptides such as transforming growth factor cause fibroblasts to migrate and specialize and have been found to cause angiogenesis.

A specific humoral mediator may promote the healing cascade in the treatment of tendinosis as well. These growth factors trigger stem cell recruitment, increase local vascularity and directly stimulate the production of collagen by tendon sheath fibroblasts.

**Table No. 1 : Age Distribution in both the groups**

<table>
<thead>
<tr>
<th></th>
<th>Local steroid injection</th>
<th>Autologous blood injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age of participants</td>
<td>42.27</td>
<td>42.9</td>
</tr>
<tr>
<td>S.D</td>
<td>9.51</td>
<td>12.8</td>
</tr>
</tbody>
</table>

Age group encountered in the study ranged from 17 years to 67 years, with a mean age of 42.6. Peak incidence at fourth decade of life was seen. The mean age of patients in autologous blood injection group was 42.9 and in corticosteroid injection group was 42.2 p value= 0.8283 which was non significant. Thus age of patients in both the groups was comparable.

**Graph 1 : Mean Age of Patients in both the groups**

**Table 2 : Sex distribution in both the groups**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Local steroid injection</th>
<th>Autologous blood injection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>13</td>
<td>13</td>
<td>26</td>
</tr>
<tr>
<td>Female</td>
<td>17</td>
<td>17</td>
<td>34</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>30</td>
<td>64</td>
</tr>
</tbody>
</table>

Out of the 60 participants, 26 were males and 34 were females. In corticosteroid injection group 13 were males and 17 were females. In autologous blood injection group 13 were males and 17 were females. p value = 1 which is non significant. Thus both the groups were comparable in terms of number of males and females in each group.

**Graph 2 : Sex distribution in both the groups Table**
Table No. 3: Elbow side involved in both groups

<table>
<thead>
<tr>
<th>Side</th>
<th>Blood</th>
<th>Steroid</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>6</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Right</td>
<td>24</td>
<td>25</td>
<td>49</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>30</td>
<td>60</td>
</tr>
</tbody>
</table>

Out of the 60 participants, 49 participants had their right side elbow affected and 11 had their left side affected.

p value = 1 which is non significant. Thus both the groups were comparable in terms of side of elbow involvement.

Graph 3: Elbow side involved in both the groups

Table No. 4: Outcome values at the time of Presentation (before injection)

<table>
<thead>
<tr>
<th>Side</th>
<th>Local corticosteroid injection</th>
<th>Autologous blood injection</th>
<th>P Value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS score</td>
<td>7.53</td>
<td>7.70</td>
<td>0.53945</td>
<td>NS</td>
</tr>
<tr>
<td>SD</td>
<td>1.2794</td>
<td>1.3429</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p value for VAS score is 0.5395 which is statistically not significant. Hence the outcome values before the injection are comparable.

Graph 4: Outcome values at the time of Presentation (before injection)

First follow up at 2nd week

Table No 5: outcome value at 2nd week

<table>
<thead>
<tr>
<th>Side</th>
<th>Corticosteroid injection group</th>
<th>Autologous blood group</th>
<th>P Value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS</td>
<td>1.40</td>
<td>3.63</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>SD</td>
<td>0.62</td>
<td>0.61</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p value for VAS score is < 0.001 which is statistically significant. Hence the decrease in pain at 2nd week is statistically significant in corticosteroid injection compared to autologous blood injection group.

Graph 5: Outcome values at 2nd week
Follow up at 2nd month

Table no 6: outcome value at 2nd month

<table>
<thead>
<tr>
<th></th>
<th>Corticosteroid injection group</th>
<th>Autologous blood group</th>
<th>p value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS score</td>
<td>1.6</td>
<td>1.73</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>S D</td>
<td>0.25</td>
<td>0.63</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p value for VAS Score is 0.001 which is statistically significant
Hence the decrease in pain at 2nd Month is statistically significant in corticosteroid injection compared to autologous blood injection group.

Graph 6: Outcome values at 2nd month Follow up

Follow up at 6 month

Table no 7: Outcome value at 6th month

<table>
<thead>
<tr>
<th></th>
<th>Corticosteroid injection group</th>
<th>Autologous blood group</th>
<th>p value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean VAS score</td>
<td>2.83</td>
<td>0.7</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>S D</td>
<td>1.83</td>
<td>0.79</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

p value for VAS Score is 0.001 which is statistically significant
Hence the decrease in pain at 6th Month is statistically significant in autologous blood injection group compared to corticosteroid injection group

Graph 7: Outcome value at 6th month

The severity of pain during the day at baseline and during follow-up at 2week, 2nd month and 6th month

Table no 8: Mean VAS score for the two groups

<table>
<thead>
<tr>
<th>Follow up period</th>
<th>Mean VAS Score</th>
<th>S D</th>
<th>Mean VAS Score</th>
<th>S D</th>
<th>p value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before injection</td>
<td>7.533</td>
<td>1.279</td>
<td>7.7</td>
<td>1.342</td>
<td>0.5395</td>
<td>N S</td>
</tr>
<tr>
<td>2nd week</td>
<td>1.40</td>
<td>0.62</td>
<td>3.63</td>
<td>0.61</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>2nd month</td>
<td>1.6</td>
<td>0.25</td>
<td>1.73</td>
<td>0.63</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>6th month</td>
<td>2.83</td>
<td>1.83</td>
<td>0.7</td>
<td>0.79</td>
<td>0.001</td>
<td>S</td>
</tr>
</tbody>
</table>

Graph 8: Mean VAS score pre and post procedure at 2nd week, 2nd month and 6th month

Complications

Table 9: Local skin atrophy

<table>
<thead>
<tr>
<th></th>
<th>Corticosteroid injection</th>
<th>Autologous blood injection</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local skin atrophy</td>
<td>yes</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>no</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

Local skin atrophy: Only two patients (6.6%) had local skin atrophy in corticosteroid injection group while no patient in autologous blood injection group had this problem.
p value=.0150 which is non-significant. There was no statistical significance related to post intervention local skin atrophy.
In this current study, the mean age encountered was 42.7 years (Range: 17 to 67 years); the peak incidence was seen from 35 to 50 years. This was seen similar in two separate studies which observed mean age of 45 and 43 years.31,81 Another study observed the mean age to be 46.5 years. 5

In this current study, out of the 60 participants, 25 (41.6%) were male patients and 35 (58.3%) were female patients. Two other studies had more number of male patients, one more study had equal number of males and female patients. 6 Contrary to other studies, more number of female patients in this current study may be due to that, females at this study area are more involved in household work which causes repetitive stress at the extensor carpi radialis brevis origin causing micro trauma, a relevant etiology for the initiation of the disease.

In this current study, out of the 60 participants, 46 (76.6%) participants had their right side elbow affected and 14 (23.4%) had their left side affected. Out of the 60 participants, 51 (85%) participants had their Dominant elbow affected and 9 (15%) had their Nondominant elbow affected. In other two studies, one had 84% of the patients with their dominant elbow affected, while in another 78.6% of the patients with their dominant side affected.

Parameters like age, sex, side of elbow involved, dominance of upper limb involved, duration of symptom and type of occupation of the patients were comparable. The mean VAS score before injection in both the groups was comparable. Mean VAS score for steroid injection group was 7.533, mean VAS score for autologous blood injection group was 7.7, P value was 0.5395. Till 2 weeks follow up, statistically significant difference between the two groups with VAS scoring was seen. Corticosteroid injection group showed statistically significant decrease in VAS score at 2nd week, 2nd month compared to autologous blood injection group.

One study showed similar results with local corticosteroid injection group, when compared with oral naproxen. 25

At 2nd month and 6th month follow up autologous blood injection group showed statistically significant decrease in VAS score compared to corticosteroid group. At 6 months follow up, mean VAS score for steroid injection group = 2.83, mean VAS score for autologous blood injection group was 0.7, P value was 0.001. At the end of 6 months 46.66% patients in corticosteroid injection group and 90% patients in autologous blood injection group were completely relieved of pain. This was highly statistically significant with a P value of <0.001.

One study reported that 22/28 patients (79%) responded to autologous blood injections with average Nirschl Scores decreasing from 6.52 to 2.0 with a mean follow up of 9.5 months.

In Corticosteroid injection group till 2 weeks there was significant improvement with 63.3% of patients completely relieved of pain. Many of these patients reported recurrences at 2nd month and 6month follow up. The rate of recurrence was 36.8% in corticosteroid injection group. Similar recurrence rate was seen in one study where 14% patients worsened in their symptoms with corticosteroid injection.

In autologous blood injection group at 2nd month follow up, 16.66% of patients were completely free of pain. At the end of 6 months there was no recurrence. This was statistically significant with a P value of <0.001. Maximum benefit reached at an average of 6.1 weeks in corticosteroid injection group. Maximum benefit reached at an average of 11.43 weeks in autologous blood injection group. This was statistically significant with a P value of 0.0003.

This study cannot prove conclusively whether the blood itself induced an inflammatory cascade or whether the injection created the problem. It is theorized that the beneficial effects of steroid injection result from the bleeding caused by forcing fluid through tissue planes at high pressures.

It was seen that there was a significant increase in post interventional pain for few days in autologous blood injection group. In corticosteroid injection group 8 participants (26%) patients complained of post intervention exacerbation of pain while in autologous injection group 18 participants (60%) complained of increase of pain after local injection. This was statistically significant with a P value of 0.009.

And these patients had to be managed with oral analgesics for varying period of days (2to7 days) for pain relief. Only two patients (6.6%) had local skin atrophy in corticosteroid injection group while no patient in autologous injection group had this problem. Between two groups there was no statistical significance related to post intervention local skin atrophy. (p = 0.150) showing that the local steroid infiltration done with proper investigations and care gives rise to negligible complication.

To conclude, autologous blood injection is beneficial both in short term and long term for the treatment of lateral epicondylitis. Advantages of autologous blood injection are - highly acceptable, efficacious, economic, easy to carry out as outpatient procedure, devoid of potential complications such as hypoglycemia, skin atrophy, tendon tears associated with corticosteroid injection and low recurrence rate.

Clinical findings such as those presented should be correlated with histologic specimens showing evidence of healing such as organization of collagen bundles and return to normal cellular activity after injections of autologous blood into areas of tendinosis. The subject bias inherent in the design of our study was unavoidable because it was difficult to blind either patient or investigator in regard to drawing and injecting autologous blood. Furthermore most patients are reluctant to donate blood that may be discarded and not used for their benefit. Nonetheless this study offers encouraging results of an alternative treatment that addresses the pathophysiology of lateral epicondylitis that has failed traditional nonsurgical modalities. Further clinical studies may prompt other investigators to further define substances that may enhance tendon healing for lateral epicondylitis and other disabling tendinoses.
CONCLUSIONS:

- Lateral epicondylitis is a common problem encountered in the orthopaedic practice.
- Even though it has been termed tennis elbow and called same routinely, it is seen to affect non-athletes rather than athletes.
- Much controversy has been there over the pathophysiology and there is not enough scientific evidence to favour any particular type of treatment for acute lateral epicondylitis.
- Currently degeneration of the origin of the extensor carpi radialis brevis (ECRB), repeated micro trauma and incomplete healing response has been accepted as the cause of lateral epicondylitis by most of the researchers.
- Histopathological reports have shown that lateral epicondylitis is not an inflammatory process but a degenerative condition termed 'tendinosis'.
- Most conservative modalities such as local corticosteroid injection have focused on suppressing inflammatory process that does not actually exist.
- Corticosteroid injection is associated with high recurrence on long term follow-ups.
- In this study autologous blood injection demonstrated a statistically significant decrease in pain compared to corticosteroid injection group even on long term follow up (6 months).
- At the end of 6 months 46.66% patients in Corticosteroid injection group and 90% patients in autologous blood injection group were completely relieved of pain.
- The duration for maximum benefit to reach is longer in autologous blood injection (11.43weeks) compared to corticosteroid injection (6.1 weeks).
- Autologous blood injection is associated with more post injection pain compared to corticosteroid injection.
- Autologous blood injection technique for lateral epicondylitis offers a better treatment with (1) its application is minimally traumatic, (2) it has a reduced risk for immunemediated rejection, devoid of potential complications such as hypoglycemia, skin atrophy, tendon tears associated with corticosteroid injection, (3) it is simple to acquire and prepare, easy to carry out as outpatient procedure and (4) it is inexpensive, (5) better relief of pain, (6) low recurrence rate.

This study offers encouraging results of an alternative treatment that addresses the pathophysiology of lateral epicondylitis that has failed traditional nonsurgical modalities.

BIBLIOGRAPHY


