



## LATERAL EPICONDYLITIS; COMPARISON OF AUTOLOGOUS BLOOD AND CORTICOSTEROID IN THE TREATMENT. A PROSPECTIVE, RANDOMIZED, CONTROLLED TRIAL

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### INTRODUCTION

Incidence of 4-7 adults per 1000 adults per 1000 per annum makes lateral epicondylitis an important condition affecting the upper extremity<sup>1-3</sup>. Can occur in any population with equal affiliation to both sex yet it has more impact on athletes and manual worker<sup>1-3</sup>. The intensity of pain may vary but it is the most common and important symptom of lateral epicondylitis. Pain is usually felt on lateral aspect of the elbow and it increases in intensity when grasping and dorsiflexion of wrist is done against resistance<sup>1</sup>. Although there are many theories regarding its etiology but degeneration of common extensor origin especially extensor carpi radialis brevis is thought to be the core reason<sup>1,3</sup>. The causative factor in this degeneration of extensor origin is repeated minor trauma that is unrecongized<sup>4,5</sup>.

**ABSTRACT... Objective:** With aging, chemical hormonal and vascular factors have their part to play in lateral epicondylitis. The objective is to compare results of autologous blood injection and corticosteroid injection in treatment of lateral epicondylitis. **Place and Location:** Out Patient Department of Peshawar Institute of Medical Sciences, Peshawar from March 2013 to February 2014. **Material and Methods:** A prospective randomized control trail conducted on 58 patients fulfilling inclusion criteria. DASH score and VAS score used as outcome measures and both were recorded before injections and at each follow up made at 2 weeks, 6 weeks, 12 weeks and 24 weeks interval. P-value was calculated where applicable. **Results:** Out of 79 patients 65 met the inclusion criteria. Mean age was 41.43 years  $\pm$  13.43. 36 were females and 29 males. Dominant elbow involved in 39 patients. Mean duration of symptoms was 7.1  $\pm$  2.9 months. 7 patients lost in follow up. DASH score improved in both groups (P value <0.0001) but when compared there was no significance difference between the two groups ( P value 0.33 at 12 weeks and 0.09 at 24 week follow up). Similarly Mean VAS improved at 12 and 24 week follow up (P value <0.0001) in both groups but when compared the difference was non-significant (P value .071 at 12 weeks and 0.12 at 24 weeks follow up). **Conclusions:** Both steroid and autologous blood injection has shown improvement in pain and physical activity and provide acceptable results although none superior to other significantly.

**Key words:** Autologous blood, Steroid, Lateral epicondylitis, Visual Analogue Scale, DASH

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In elderly patients occupation related physical activity while in younger patients sports related activities result in such trauma<sup>1,4,5</sup>. At microscopic level this condition is characterized by vascular hyperplasia, fibroblast proliferation and disorganized collagen fibers but no evidence of inflammation<sup>6-8</sup>.

Conventionally lateral epicondylitis is treated by many surgical and non-surgical method that included rest, physical therapy, brace, drugs, corticosteroid injections, laser therapy and extra corporeal shock wave therapy<sup>1,2</sup>. Non-surgical therapies lack consistent effects<sup>2,9-11</sup> and hence opens the option of surgical treatment which include open, percutaneous or arthroscopic debridement of the involved area<sup>1,12</sup>.

Research in recent years has shown that blood contents especially platelets not only causes increase in tissue regeneration and healing but also causes removal of necrotic tissue, all through release of few proteins which in turn attracts macrophages, mesenchymal stem cells and osteoblasts<sup>13</sup>. Use of autologous whole blood injection was first described by Edwards and Calandruccio and showed promising results in lateral epicondylitis<sup>2,14</sup>. This injection delivers growth factors present in blood to injury area and this blood then act as catalyst and mediator to promote tissue repair and regeneration<sup>6</sup>. Comparative studies of autologous blood injection with corticosteroid injection has shown better outcome in former group<sup>15</sup>. The purpose of this study is to compare the both methods of treatment and evaluated the outcome.

## MATERIAL & METHODS

Fifty eight patients diagnosed clinically with lateral epicondylitis and fulfilling the inclusion criteria (Table-I) in Out Patient Department of Orthopaedic Department, Peshawar Institute of Medical Sciences, Hayatabad, Peshawar, from March 2013 to February 2014 were included in the study after getting approval from head of department. Informed consent was taken from all the participants. Patients were randomized into 2 treatment groups' i.e. steroid injection and autologous blood injection group by sealed envelopes generated centrally by a random numbers table. In afford to keep study participants unaware of study protocol, we drawn 3ml blood from each participant before injection was prepared. Injection was mixed with 1% lignocaine by the physician, who stayed behind a curtain or screen and then covered the syringe with foil so that participant didn't know about the contents of syringe. Before injection the patient was asked to fill out two questionnaires: the DASH and Visual Analog Scale for pain. DASH (Disability of the Arm, Shoulder and Hand) score was used as primary outcome measure. "The DASH is a 30-item self-report questionnaire designed to measure physical function items-". "The DASH is designed to measure physical disability and symptoms in a heterogeneous population that

includes both males and females; people who place low, moderate, or high demands on their upper limbs during their daily lives (work, leisure, self-care); and people with a variety of upper-limb disorders<sup>16</sup>". At least 27 of the 30 items must be completed for scoring. Currently the literature holds 12.7 point change to be statistically significant at 95% confidence interval<sup>17</sup> and is called Minimum Detectable Change (MDC) while change of 15 points is considered clinically significant and is called Minimum clinically important difference (MCID)<sup>17</sup>. Thomsen provocative test to elicit pain was used as secondary outcome measure. The Thomsen provocation test was performed with the shoulder flexed at 60°, the elbow extended, the forearm pronated, and the wrist extended to 30°. Pressure was applied on the dorsum of the hand. The test was performed with the patient recording the pain on a 100-mm visual analog scale (VAS) with 0 indicating no pain and 10 indicating maximum pain. At follow-up, a 50% decrease in the Thomsen test VAS value was considered a successful result.

By observing all antiseptic techniques the content of injection was injected by introducing the needle into lateral epicondyle of humerus at site which is most tender. A "peppering" technique was used for injection which means to insert the needle, inject some content into area, then withdrawing the needle but not emerging from skin and after redirecting slightly reinserting again and injecting the content. Patients are advised to avoid those activities which require repetitive movements of wrist and elbow during first 3 weeks after injection. As soon as the pain permits, gentle passive stretching exercises of extensor muscles of forearm started. Patients were followed up at 2 weeks, 6 weeks, 12 weeks and 24 weeks interval and evaluation was done with same questionnaires that were used before injection i.e. DASH score and VAS score. Statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS 16.0; SPSS, Inc, Chicago, Illinois). P-value of < 0.05 deemed to indicate statistical significance and was calculated where applicable.

## RESULTS

Out of 79 patients that we received with diagnosis of lateral epicondylitis, 65 met the inclusion criteria. Mean age of the patients was 41.33 years  $\pm$  13.43. 29(44.61%) of these patients were females and 36 (55.38%) were males. Dominant elbow was involved in 39(60%) patients. Mean duration of symptoms of lateral epicondylitis was 7.1  $\pm$  2.9 months. During follow up 7 patients were lost (4 females and 3 males). 58 remaining patients were randomized to autologous blood group and steroid group with 29 patients in each group. All patients received the respective injection according to protocol. Mean DASH score in both groups just before respective injection and then at 2 week, 6 week, 12 week and 24 week follow up is given in Table II. Currently the literature holds 12.7 point change to be statistically significant at 95% confidence interval<sup>17</sup> and is called Minimum Detectable Change (MDC) while change of 15 points is considered clinically significant and is called Minimum clinically important difference (MCID)<sup>17</sup>. In our study both groups had change of >17 points at 12 and 24 weeks follow up respectively which means it is statistically as well as clinically significant. In autologous blood injection group DASH Score reduces from 87  $\pm$  18.64 to 59  $\pm$  15.45 (P value <0.0001) at 12 weeks and to 41  $\pm$  15.13 (P value <0.0001) at 24 weeks post injection. Similarly in steroid injection group DASH Score reduces from 84  $\pm$  18.76 to 63  $\pm$  15.65 (P value <0.0001) at 12 weeks and to 48  $\pm$  14.99 (P value <0.0001) at 24 weeks post injection. Similarly pre and post injection (at 2, 6, 12 and 24 weeks) mean Visual Analogue Pain Score on Visual Analogue Pain Scale for is given in Table III. In both groups there is reduction in Visual Analogue Pain Score on each subsequent follow up. In autologous blood injection group Visual Analogue Score for pain reduces from 7.21  $\pm$  2.01 to 3.23  $\pm$  2.12 (P value <0.0001) at 12 weeks and to 1.57  $\pm$  0.91 (P value <0.0001) at 24 weeks post injection. In steroid injection group Visual Analogue Score for pain reduces from 7.34  $\pm$  1.99 to 3.43  $\pm$  1.97 (P value <0.0001) at 12 weeks and to 1.96  $\pm$  1.01 (P value <0.0001) at 24 weeks post injection. When DASH and Visual Analogue Score of autologous blood

injection group is compared to steroid injection group at time just before injection and then at 12 and 24 week post injection, the difference is non-significant (Table II).

Inclusion criteria	
•	18 years of age
•	A history of lateral epicondylitis for a minimum of 6 months
•	Tenderness on palpation of the lateral epicondyle
•	40 mm on the visual analog scale (Thomsen Provocative test)
Exclusion criteria	
•	Pregnancy
•	Local corticosteroid injection for lateral epicondylitis
•	Cervical spondylosis, carpal tunnel and radial Nerve entrapment
•	History or radiograph of the upper extremity and elbow arthritis
•	Rheumatologic disease or Severe systemic illness
•	Previous surgery or elbow dislocation

**Table-I. Inclusion and Exclusion criteria**

Time Point	Blood injection (Mean[SD])	Steroid injection (Mean[SD])	P-Value
Initial	87+18.64	84+18.76	0.53
2 weeks	81+19.11	77+19.21	0.43
6 weeks	78+16.21	73+16.79	0.25
12 weeks	59+15.45	63+15.65	0.33
24 weeks	41+15.13	48+14.99	0.09

**Table-II. DASH Scores (n=58)**

Time Point	Blood injection (Mean[SD])	Steroid injection (Mean[SD])	P-Value
Initial	7.21+2.01	7.34+1.99	0.80
2 weeks	6.98+1.78	6.65+1.64	0.47
6 weeks	5.42+1.34	5.21+1.23	0.54
12 weeks	3.23+2.12	3.43+1.97	0.71
24 weeks	1.57+0.91	1.96+1.01	0.12

**Table-III. Visual analogue pain scale (n=58)**

## DISCUSSION

With aging, chemical hormonal and vascular factors having their part to play, lateral epicondylitis is considered to be having multifactorial pathophysiology and etiology<sup>1</sup>. Along with other treatment options steroid injection and autologous blood injection are used for treatment purpose, steroids being most common of these

two<sup>3</sup>. Steroid injection causes hemorrhage<sup>18</sup> in the tissue plans and hence influences the degenerative as well as reparative components in lateral epicondylitis<sup>1</sup>. Autologous blood injection basically delivers growth factors at the injury site directly and hence augments natural healing process and tendon repair<sup>6</sup>. Along with lateral epicondylitis autologous blood injection is also used in other tendinopathies and has shown at least comparable results with steroid injection<sup>3</sup>. In few studies it is shown that cases refractor to steroids have improved with autologous blood injection<sup>6</sup>. Patients seek medical attention in lateral epicondylitis for pain and limitation of daily activity and treatment is also evaluated by significant change in these two symptoms. To achieve reduction in pain and improvement in daily physical activity, number of treatment modalities are use ranging from physiotherapy, rest, NSAIDs, steroid injections, autologous blood injections, plasma rich platelet to surgery<sup>1-3,6,13</sup>.

DASH score is used to range the amount of disability caused by lateral epicondylitis and re-evaluation of this score after treatment of condition gives us good indicator of showing if improvement has achieved with particular management plan. In our study DASH score showed significant improvement at 12 and 24 week follow up (P value <0.0001) in both groups individually. The DASH had change of 28 and 46 points after autologous blood injection and 21 and 36 point after steroid injection at 12 and 24 week follow up respectively which according to Beaton DE<sup>17</sup> is significant both statistically and clinically with 95% confidence interval. But when both groups compared to each other it showed no significant difference in the primary outcomes measure and DASH score among these 2 modalities (P value 0.09). This finding is in line with study of Wolf JM et al<sup>3</sup>.

In our study the patients VAS score for pain after steroid injection has improved significantly (P value <0.0001) from  $7.34 \pm 1.99$  to  $1.96 \pm 1.01$ . Patients VAS score for pain after autologous blood injection has also improved significantly (P value <0.0001) from  $7.21 \pm 2.01$  to  $1.57 \pm 0.91$ . This

shows that both steroid and autologous blood injection causes significant reduction in pain (P value <0.0001 in both groups). When compared the two groups with each other the P value came out to be 0.12 at 24 weeks follow up. The findings of the current randomized, controlled trial comparing autologous blood with corticosteroid injection showed no differences in the secondary outcomes measure and VAS score among these 2 modalities although both modalities causes reduction in pain significantly. Wolf JM et al<sup>3</sup> in his comparative study had improvement of VAS pain score from 5 to 3 in autologous blood injection group and from 5 to 2 in steroid group. Other studies around the globe has also found comparable results with improvement in VAS pain score with autologous blood injection and steroid injection<sup>1,2,6</sup> but showed no preference of autologous blood injection over steroid injection and vice versa<sup>1,2,3,6</sup>.

The primary limitation of this study is the small sample size and the primary reason for this is difficulty in enrolling patients to autologous blood injection as large portion of our population is illiterate and stubborn to new ideas. In addition, loss of 8 patients who enrolled but did not complete the study may have affected results as well to some extent. Bias can also get introduced when Physicians performing the injections were not blinded to the type of injection given. Overall, the treatment groups are small, which may have affected the comparative analysis.

## CONCLUSIONS

Although autologous blood injection show no significant superiority over steroid blood injection it has shown improvement in pain and physical activity comparable with steroid injection and even better to an extent. Also it has advantage of lower cost and no requirement of additional equipment while provide acceptable short to long term results.

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