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A Comparative Study on the Efficacy of Local Infiltration of Autologous Blood versus Local Corticosteroid Infiltration for the Treatment of Chronic Lateral Epicondylitis Elbow

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Abstract: *Musculoskeletal disorders are common problems in primary health care. Chronic painful tendon disorders are common in both athletic and sedentary individuals[1,2]. Lateral epicondylitis is relatively more common among working-age individuals in the general population[3]. Typical signs and symptoms include pain and tenderness over the lateral epicondyle, exacerbated by resisted wrist extension and passive wrist flexion, and impaired grip strength. This study aims to find whether autologous blood provides comparable functional outcome over local steroids and hence whether it can replace steroids in treatment of tennis elbow. Patients with non traumatic elbow pain attending the Orthopaedics Out Patient Department of Jubilee Mission Medical College Hospital from January 2013 to August 2014. The participating subjects were randomly grouped into two groups [Steroid (Group A) & Autologous Blood (Group B)] according to a random number table. Pain in the subject's affected elbow was measured using Visual Analogue Score (VAS) and the functional status of their affected elbow was measured using Patient-Rated Tennis Elbow Evaluation (PRTEE) Score and Mayo Elbow Performance (MEP) score. Initially both the groups had comparable initial VAS scores. At 1 month follow up, steroid group showed a significantly greater improvement in mean VAS scores when compared to autologous blood group p value 0.001. However at 6 months follow up, steroid group showed no statistically significant difference in mean VAS scores when compared to autologous blood group , p value 0.7. Average PRTEE score and average MEP score at 6 months showed no difference statistically. From the current study we concluded that both local corticosteroid and autologous blood were equally efficacious in the treatment of chronic lateral epicondylitis of elbow.*

I. Introduction

Musculoskeletal disorders are common problems in primary health care. They are the most common work-related disease, with high costs incurred from long-term disability. Chronic painful tendon disorders are common in both athletic and sedentary individuals[1,2]. Lateral epicondylitis is relatively more common among working-age individuals in the general population[3]. Lateral epicondylitis has been found to be the second most frequently diagnosed musculoskeletal disorder of the upper extremities in a primary health care setting[4]

Tennis elbow or lateral epicondylitis refers to a syndrome of pain centred over the common origin of the extensor muscles of the fingers and wrist at the lateral epicondyle. Typical signs and symptoms include pain and tenderness over the lateral epicondyle, exacerbated by resisted wrist extension and passive wrist flexion, and impaired grip strength. It occurs more commonly in non-athletes than athletes and has a peak incidence in the fifth decade. The initial treatment is with rest, modification of activity and local splint. Local injection of corticosteroids comes next if the initial treatment is found to be unsatisfactory.

Another novel modality of treatment is the local administration of growth factors. These growth factors are administered in the form of autologous whole blood or platelet-rich plasma (PRP). The degranulation of the alpha-granules in the platelets releases many different growth factors that play a role in tissue regeneration processes.

II. Aims And Objectives

In the treatment area of lateral epicondylitis, there exist several different treatments, with varying side effects. Local injection of corticosteroids has been "the treatment" for tennis elbow for long. Despite its local complications it is still preferred over other treatment modalities by many orthopaedicians. But there is growing mound of evidence in the current literature which states that there is absence of an inflammatory component in lateral epicondylitis. So the treatment by local steroids need to be re-evaluated as steroid treatment is based on the premises that the major pathological factor in tennis elbow is inflammation. Moreover; studies show conflicting evidence about their efficacy and there are some complications too. In a study by Jobe and Cicotti[5], it

was found that superficial injection of corticosteroid may result in subcutaneous atrophy and that intra tendinous injection may lead to adverse changes within the ultrastructure of the tendon. The use of autologous growth factors seems to be promising in the treatment of this disease. It is thought to lead to tendon healing through collagen regeneration and the stimulation of a well-ordered angiogenesis. It is obtained from autologous blood and is a cheap and readily available alternative to steroids. This study aims to find whether autologous blood provides comparable functional outcome over local steroids and hence whether it can replace steroids in treatment of tennis elbow.

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
3. its application is minimally traumatic
4. it is simple to acquire and prepare, easy to carry out as outpatient procedure
5. it is inexpensive[6,7]

III. Materials And Methods

Study design

Prospectiveinterventional cohort study.

Study population

Patients with non traumatic elbow pain attending the Orthopaedics Out Patient Department of Jubilee Mission Medical College Hospital.

Study setting

Jubilee Mission Medical College & Research Institute, Thrissur, Kerala, India.

Duration of study

A period of 20 months from January 2013 to August 2014

Inclusion criteria

Patients between 18 - 60 years of age diagnosed of having chronic lateral epicondylitis attending the Orthopaedics Out Patient Department of Jubilee Mission Medical College Hospital.

Exclusion criteria

1. Pain less than 6 months duration
2. History of trauma
3. Patients having local infection over the lateral aspect of elbow
4. Patients who had previously taken local steroid injection or local autologous blood or PRP infiltration for the treatment of lateral epicondylitis
5. Patients with history of surgery for LE
6. Effusion of the elbow
7. Radiculopathy due to cervical spine pathology
8. Entrapment of the ulnar nerve
9. Periarticular fracture elbow

Statistics and Sample size

Based on 95% CL, and Type 1 error at 5%, calculated sample size is 100 (2 groups of 50 subjects each), randomized, computer generated random number table used. Statistical data analysis, mean±SD (standard deviation), Percentage, Chisquare test, Non paramentric statistical tools were used all statistical test the $p<0.05$ considered as statistically significant.

IV. Methodology

All patients attending Orthopaedics Out Patient Department of JMMC & RI diagnosed of having chronic lateral epicondylitis were informed about the study and a written consent was obtained from those willing to participate in the study. Then the participating subjects were randomly grouped into two groups [Steroid (Group A) & Autologous Blood (Group B)] according to a random number table. Pain in the subject's affected elbow was measured using Visual Analogue Score (VAS) and the functional status of their affected elbow was measured using Patient-Rated Tennis Elbow Evaluation (PRTEE) Score and Mayo Elbow Performance (MEP) score.

V. Procedure

Subjects were made to lie supine. The affected elbow was thoroughly cleaned with Povidone Iodine

and Surgical Spirit and allowed to dry. The point of maximum tenderness over the common extensor origin area was identified by palpation and 2 ml (80 mg) of Methyl Prednisolone Acetate (Inj. DEPOMEDROL® was infiltrated locally into that point of subjects belonging to Group A. Under strict aseptic precautions; 2 m1 of blood was drawn from subjects belonging to Group B via venepuncture using a 21 gauge needle from the contralateral antecubital fossa and it was infiltrated locally into their affected elbow as described earlier. All the subjects were observed for 1 hour for any acute adverse effects. Following the procedure they were allowed to ice the elbow and take paracetemol as necessary, but to avoid anti-inflammatory drugs. No local anaesthetics were used. Pain in the subjects elbow was reassessed after 1 month and again at 6 months using VAS. The functional status of the subjects elbow was also reassessed along with it using PRTEE and Mayo Elbow Performance scores. Any subject complaining of breakthrough pain while under follow-up was managed by oral paracetamol only. Subjects were advised not to take any other analgesics during the study period. All injections were given by the same operator.

Diagnostic criteria

- Pain over lateral epicondyle for more than 6 months; especially during wringing movements and forced dorsiflexion of the hand.
- Tenderness over the lateral epicondyle and the common extensor origin.
- A positive "chair lifting test" or the "coffee cup test"[8] in which the patient feels pain at the lateral epicondyle when picking up a full cup of coffee
- Positive "Mills' test"[9] in which full pronation combined with complete
- wrist and finger flexion prevents full elbow extension or, at least, a feeling of resistance at the elbow and pain at the lateral epicondyle
- Positive "Maudsley's test"[10] or the "middle-finger test", in which resisted extension of the middle finger when the elbow is fully extended and the forearm is pronated causes pain at the lateral epicondyle.

VI. Results

Age group encountered in the study ranged from 24 years to 54 years, with a mean age of 40.62±10.2 in steroid injection group and 38.36±9.8 in autologous blood injection group. Peak incidence at fifth decade of life was seen in steroid injection group and at fourth decade was seen in autologous blood injection group. The mean age of patients in steroid injection group was 40.62 and in autologous blood injection group was 38.36; p value= 0.15 which was not significant. Thus age of patients in both the groups was comparable.

Out of the 100 participants, 54 were males and 46 were females. In steroid injection group, Male 28 (56%) and Females 22 (44%) and autologous blood injection group, Male 26 (52%) and Females 24(48%) patients respectively; P value > 0.05 (0.54) which is not statistically significant. Thus both the groups were comparable in terms of number of males and females in each group.

Prevalence of Diabetes Mellitus and Prevalence of Hypertension showed no significant difference between the two groups The mean duration of symptoms in patients with lateral epicondylitis in steroid injection group and autologous blood group were 1.92 Years and 1.92Years respectively. P value was 0.916 which means there is no significant difference between the two groups regarding mean duration of symptoms.

Initially both the groups had comparable initial VAS scores. At 1 month follow up, steroid group showed a significantly greater improvement in mean VAS scores (26.0; from 65.6 to 39.6, 39.6%) when compared to autologous blood group (7.4; from 65.2 to 57.8; 11.3%); p value 0.001. However at 6 months follow up, steroid group showed no statistically significant difference in mean VAS scores (36.0; from 65.6 to 29.6, 54.9%) when compared to autologous blood group (36.4; from 65.2 to 28.8; 55.8%); p value 0.79.

The initial mean PRTEE pain score of both the groups showed comparable initial mean PRTEE pain scores. At 1 month follow up, steroid group showed no statistically significant difference in mean PRTEE pain scores when compared to autologous blood group; p value 0.61. At 6 months follow up also, steroid group showed no statistically significant difference in mean PRTEE pain scores when compared to autologous blood group; p value 0.81.

The initial mean PRTEE score (for Functional Disability on Specific Activity) of both the groups showed comparable initial mean PRTEE (for Functional Disability on Specific Activity) scores. At 1 month follow-up, steroid group showed no statistically significant difference in the above said score when compared to autologous blood group; p value 0.71. However at 6 months follow-up, there was a statistically significant difference in mean PRTEE score (for Functional Disability on Specific Activity) between the two groups; p value 0.001. Patients belonging to autologous blood group had a better outcome compared to the patients treated with steroid injection.

The initial mean PRTEE score (for Functional Disability on usual Activity) of both the groups had comparable initial scores. At 1 month follow-up, steroid group showed no statistically significant difference in

the above said score when compared to autologous blood group; p value 0.79. At 6 months follow-up also, steroid group didn't have a statistically significant difference in that score when compared to autologous blood group; p value 0.65.

The initial average PRTEE score of patients treated with steroid was 62.52 and that of patients treated with autologous blood was 62.79; p value 0.92. This means both the groups had comparable initial average PRTEE scores. At 1 month follow-up, steroid group showed no statistically significant difference in average PRTEE scores when compared to autologous blood group; p value 0.60. At 6 months follow-up, there was a statistically significant difference in average PRTEE scores between the two groups; p value 0.04. the patients belonging to autologous blood group fared better.

Though the MEP Pain score, MEP ROM, MEP Function scores and MEP Stability scores of patients treated with steroid and patients treated with autologous blood were comparable initially; the scores didn't show any statistically significant difference at 1 month follow-up and at 6 months follow-up.

The initial average MEP score of patients treated with steroid was 74.20 and that of patients treated with autologous blood was 75.80; p value 0.63. This means both the groups had comparable initial average MEP scores. At 1 month follow-up, steroid group showed no statistically significant difference in average MEP scores when compared to autologous blood group; p value 0.56. At 6 months follow-up also, steroid group showed no statistically significant difference in average MEP scores when compared to autologous blood group; p value 0.67.

VII. Discussion

In this current study, the mean age encountered was 42.7 years (Range: 24 to 54 years); the peak incidence was seen from 30 to 50 years. This was seen similar in two separate studies which observed mean age of 45 and 43 years[11]. Another study observed the mean age to be 46.5 years[6]. In this current study, out of the 100 participants, 54 were male patients and 46 were female patients. Two other studies had more number of male patients[10]. One study had equal number of males and female patients[7].

Parameters like age, sex, duration of symptoms 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 65.6, mean VAS score for autologous blood injection group was 65.2, p value was 0.82. At 1 month 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 1 month compared to autologous blood injection group. One study showed similar results with local corticosteroid injection group, when compared with oral naproxen[10].

A prospective, double-blinded, randomised trial by Creaney *et al*[11] published in British Journal of Sports Medicine 2011 compared the effectiveness of PRP versus autologous blood. The main outcome measure was PRTEE. At 6 months the authors observed a 66% success rate in the PRP group versus 72% in the autologous blood group. There was a higher rate of conversion to surgery in the autologous blood group (20%) versus the PRP group (10%). Our study results are in agreeance with the above mentioned study in regard to improvement in function scores in the autologous blood group; though our study didn't compare PRP with autologous blood. The major disadvantage regarding studies including PRP is that there are no definite standardised means for extracting PRP.

A study by Kazemi M, Azma K, Tavana B, Rezaiee Moghaddam F, Panahi A[12] compared local corticosteroid with autologous blood injections for the short-term treatment of lateral elbow tendinopathy. Inter - group analyses at 4 weeks showed superiority of autologous blood for severity of pain (P = 0.001), pain in grip (P = 0.002), pressure pain threshold (P = 0.031), and Quick DASH questionnaire score (P = 0.004). They concluded that autologous blood was more effective in short term than the corticosteroid injection. When comparing with the above mentioned study; our study had conflicting results as far as VAS scores are concerned but there was no significant difference in short term with regard to PRTEE score and MEP the two groups.

However, our study had results comparable to that of a study by Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I[13]and a meta analysis by Barr S, Cerisola FL, Blanchard V where Corticosteroid injection provided a high success rate in the short term.

VIII. Limitations Of The Study

1) Hand dominance was not taken into consideration
2) Imaging measures (MRI and ultrasound) are useful in visualizing the pathophysiology of LE. However, as the severity of the pathophysiology is not related to pain and function, imaging measures may not provide the best clinical assessment.
3) Lack of muscle strength evaluation which might have the potential to monitor progress in LE.
4) As evidence of efficacy exists for both of these methods[14-16], it was not considered ethical to include an inactive placebo control group. The lack of a placebo group in this study, or blinding of the investigator and

the patient, means that a placebo effect from these injections cannot be ruled out with certainty. Introduction of bias at the treatment stage cannot also be ruled out with certainity.

5) Ultra sound guidance while administering autologous blood or steroid; if available would have yielded much more meaningful results.

Complications

No complications were observed in any of the patients in the study population during the study period.

Conclusion

From the current study we concluded that both local corticosteroid and autologous blood were equally efficacious in the treatment of chronic lateral epicondylitis of elbow.

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