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Randomized controlled trial comparing local autologous blood injection and polidocanol injection for treatment of lateral epicondylosis of elbow

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Abstract

Background: Lateral epicondylosis has been found to occur in approximately 2% of general population. It's etiology and management still remains controversial. Various studies have shown benefits with local injection of autologous blood and polidocanol individually. However, there is paucity of studies comparing the results between these both, hence we envisage to compare the clinical and functional outcomes of local autologous blood versus polidocanol injection for the treatment of lateral epicondylosis of elbow.

Materials and methods: 60 patients (age group- 18 to 60 years)with clinically diagnosed lateral epicondylosis of elbow were enrolled for the study. They were randomized into 2 groups. Group I (n = 30) was treated with autologous blood injection and Group II (n = 30) with polidocanol injection after Nirschl staging. Patients were evaluated clinically at 6& 12 weeks after the injection and were again staged by Nirschl staging on both the visits.

Results: 34 patients successfully completed 12 weeks follow-up and were included in the analysis. It was observed that clinical outcomes in terms of Nirschl score at 6 and 12 weeks was better in Group I as compared to Group II. Statistical comparison between the two groups revealed that mean values of Nirschl score were lower in group I (4.41+1.004 and 3.71+1.532 at 6 weeks and 12 weeks of follow-up respectively) as compared to group II (4.76+1.300 and 4.47+1.281at 6 weeks and 12 weeks follow-up respectively). Down staging of disease symptom was clinically better in group I (16/17) as compared to group II (11/17). However the difference in the mean values of Nirschl score between the groups was not statistically significant (p=0.342).

Conclusion: Although autologous blood injection showed a better clinical improvement as compared to polidocanol injection, the difference was not statistically significant between these both.

Keywords: Lateral epicondylosis, Autologous blood injection, Polidocanol injection

Introduction

Lateral epicondylosis of elbow is a chronic symptomatic degeneration of the tendon rather than an inflammatory condition that affects the common attachment of the tendons of the extensor muscles of the forearm to the lateral epicondyle of the humerus [3]. It has been found to occur in approximately 2% of general population [1,2,3,4].

Although lateral epicondylosis is a self-limiting condition with resolution of symptoms in 6-24 months, multiple treatment modalities are known to improve patient outcomes in short term [2]. However, very few methods have been scientifically proven to be effective and there is a lack of evidence to prove one better than the another. Several factors that can affect the outcome which leads to inadequacy of pathophysiological data [5,6]. Despite the high prevalence of lateral epicondylosis, the development of a single effective and consistent management remains an unrealized goal [7].

The various studies have shown benefits with local autologous blood injection and polidocanol injection [1,3,8]. To the best of our knowledge, there is no study comparing the clinical and functional outcomes of treatment of lateral epicondylosis by autologous blood versus polidocanol, hence we wish to carry out this study.

Materials and methods

Ethical clearance was obtained from the ethical committee. The study was conducted in the department of Orthopaedics, GTB hospital, Delhi from December 2013 to April 2015. 60 patients between the age group of 18-60 years of either sex with pain on the lateral side of elbow for more than 3 months despite analgesic therapy and has not been treated by any prior injection therapy were included for the study. The patients with

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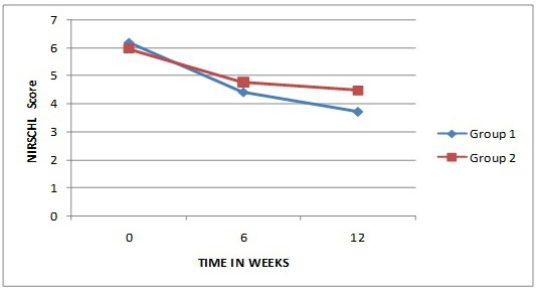

Figure 1: The mean Nirschl score

history of fracture or surgical intervention around the elbow or with any local sign of infection at the proposed injection site and known allergy to polidocanol were excluded. Detailed history was obtained regarding the presence of pain on the lateral aspect of the elbow during daily activities for more than 3 months and/or tenderness at the lateral epicondyle of humerus during resisted dorsiflexion of the wrist and middle finger with the elbow in extension. Standard AP and lateral views of elbow were obtained in all cases to rule out any other cause of elbow pain. After taking informed consent, the subjects were randomized into two groups as per plan generated by www.randomization.com.

KEY TO MASTER CHART

Random grp=Randomization group
1= Autologous blood
2= Polidocanol

Sex 1= Male
2= Female
Nirs pre intvn= Nirschl score at pre-intervention
Nirs 6wk= Nirschl score at 6 weeks of follow up
Nirs 12wk= Nischl score at 12 weeks of follow-up

Group I

After Nirschl staging, 1 ml of 2% lignocaine was injected at the most tender point of lateral epicondyle of humerus under sterile conditons. After 5 minutes, patient was injected with 2 ml of autologous venous blood taken from contralateral antecubital fossa.

Group II

After Nirschl staging, patient was injected with 0.5 to 1 ml of polidocanol by 22 gauge needle under sterile conditons.
After injection, patient was advised to perform routine activities. Patient was advised to take analgesics only if necessary and restrain from activities involving repetitive movements of wrist and elbow during initial 3 weeks after the injection. Gentle passive stretching exercises of the extensor group of muscles of forearm were started as soon as the pain permitted. Patients were evaluated clinically at 6 weeks & 12 weeks after the injection using Nirschl score (Table 1).

Statistical analysis

The minimum sample size required for this study was 30 in each group which was calculated on the basis of change in Nirschl score. The significance of difference between the two groups was obtained by using Repeated measure ANOVA test and Tukey test as applicable for following variables- Nirschl score at pre-intervention and at 6 weeks and 12 weeks of follow-up in either groups.

Table 1: Master chart

Sr. No.	Age	Sex	Random group	Nirschl pre intervation	Nirschl 6 week	Nirschl 12week
1	38	1	2	6	4	4
2	33	2	2	7	6	5
3	34	1	1	7	3	1
4	45	2	1	7	3	3
5	40	2	1	6	5	5
6	40	2	2	6	6	5
7	35	2	1	5	5	5
8	27	2	2	7	5	4
9	37	2	2	7	5	5
10	40	2	1	4	3	1
11	22	2	1	7	5	6
12	58	1	1	6	5	4
13	29	2	2	7	1	1
14	40	2	1	7	6	5
15	32	1	2	5	4	4
16	45	2	2	5	5	5
17	40	2	1	7	5	5
18	36	1	2	6	5	6
19	40	2	2	6	5	6
20	45	2	1	7	5	3
21	40	2	2	7	5	6
22	39	2	2	5	4	5
23	45	1	1	6	4	4
24	40	2	1	5	3	3
25	38	2	1	6	5	4
26	35	1	2	6	4	3
27	32	2	2	5	5	5
28	37	1	1	7	5	4
29	36	1	1	5	3	1
30	50	2	1	6	5	5
31	36	1	2	6	6	3
32	37	1	2	5	4	4
33	30	2	1	7	5	4
34	35	2	2	5	7	5

Results

Out of 60 patients, 34 patients successfully completed 12 weeks follow-up and were included in the final analysis and 26 patients were lost to follow-up. Out of these 34 patients, 17 patients (Average age 39.71 years with range 22-58 years, 29.4% males and 70.6% females) received local autologous blood injection and 17 patients (Average age 35.94 years with range 27-45 years, 35.3% males and 64.7% females) received local polidocanol injection. Thus there was no significant difference in mean age between the groups (p value=0.098). Female patients dominated in both the groups with 70.6% of female patients (12/17) in group I and 64.7% (11/17) in group II. There was no significant difference in sex distribution between the groups (p value=0.714).

Out of total 34 patients, 3 patients (case No. 18, 19 & 22) initially improved clinically and functionally at 6 weeks of follow-up, however at 12 weeks of follow-up, they deteriorated back to the pre-injection state as per Nirschl score. All these 3 patients belonged to group II.

3 patients (case no. 7, 16 and 27) showed no clinical and functional improvement i.e. Nirschl score was same at pre-intervention, 6 weeks of follow-up and 12 weeks of follow-up. Out of them, 1 patient (case no. 7) belonged to group I & 2 patients (case no. 16 and 27) belonged to group II.

1 patient (case no. 34) deteriorated clinically and functionally at 6 weeks of follow-up but at 12 weeks of follow-up, patient improved to pre-intervention state as per Nirschl score. The patient belonged to group II.

Group I-

The mean decrease in the values of Nirschl score at 6 weeks and 12 weeks of follow-up after local autologous blood injection was significant (p value=0.001) (Table 2).

Group II-

The mean decrease in the values of Nirschl score at 6 weeks and 12 weeks of follow-up after local polidocanol injection was significant (p value=0.001) (Table 2).

The above observations reveal that both autologous blood and polidocanol injections independently gave a significant pain relief and down staged the disease symptoms in the short term follow-up in both groups i.e. 16/17 patients in group I and 11/17 patients in group II.

Between group analysis:

The mean Nirschl scores were plotted on line diagram which shows the decreasing trend in the values of Nirschl score in both the groups over a period of 12 weeks (Fig. 1).

Statistical comparison between the groups revealed that mean values of Nirschl score were lower in group I as compared to group II at 6 weeks and 12 weeks of follow-up. However the differences in the mean values of Nirschl score between the groups were not statistically significant.(p=0.342)(Table 3).

Discussion

Injection therapies for lateral epicondylosis of elbow represent a crucial minimally invasive modality on the spectrum between conservative therapies and surgery. The choice of which injection to offer to patients, however is not clearly defined [3].

The mean age in our study was 39. 71 years in group I and 35.94 years in group II which is consistent with the literature [8,9,10,12,13,14,15,16,17].

Nirschl score was used in the assessment of clinical and functional outcomes in lateral epicondylosis of elbow by Edwards et al [11], Gani et al [15] and Jindal et al [9].

Jindal et al [9] conducted a Randomized controlled trial in 2013 comparing autologous blood and steroid injection in lateral epicondylosis with 25 patients in each group. Nirschl score improved from a mean score of 4.84+0.94 to 2.40+1.15 at 6 weeks of steroid injection and from a mean score of 4.52+1.23 to 1.40+1.22 at 6 weeks of autologous blood injection. The mean reduction in Nirschl score at different time points was significant. Mean age of patients in autologous blood group was 39.04 years and in steroid group was 37.32 years.

Edwards et al [11] conducted a Prospective case series in 2003 and found that after receiving 1 to 3 injections of autologous blood, pain scores and Nirschl scores decreased with complete pain relief in 79% of patients at an average follow-up of 9.5 months.

Gani et al [16] conducted a Prospective case series in 2007 in which autologous blood injection was used in patients of lateral epicondylosis. Nirschl score improved (p=<0.05) from a mean score of 5.5 to 2.1 at 35 weeks in the patients with a mean age of 34 years. Pain improved (p=<0.05) by 2.1 points at 35 weeks.

Kazemi et al [13] conducted a Randomized controlled trial in 2010 and showed that autologous blood injection was statistically more effective than steroid injection in lateral epicondylosis of the elbow at decreasing pain scores and increasing quick DASH (The Disabilities of Arm, Shoulder and Hand) scores at 8 weeks of follow-up with a mean age of 47 years .

Ozturan et al [12] conducted a Randomized controlled trial in 2010 and showed that steroids were better at 4 weeks of follow-up but autologous blood and ESWT (Extra-corporeal shock wave therapy) were better at 1 year of follow-up. The mean age of patients in this study was 45 years.

Wolf et al [10] have also shown that VAS and DASH scores improved after autologous blood injection in lateral epicondylosis over 6

Table 2: Evaluation of outcomes (Nirschl score) in both groups at different time points

Group	Pre-intervention	At 6 weeks of follow-up	At 12 weeks of follow-up	p-value
I (n=17)	6.18±0.951	4.41±1.004	3.71±1.532	0.001
II (n=17)	5.94±0.827	4.76±1.300	4.47±1.281	0.001

Table 3: Evaluation of outcomes (Nirschl score) between groups

Group 1	Group 2	p-value
Autologous blood injection (n=17)	Polidocanol injection (n=17)	0.342

months of follow-up.
Cornell et al [15] showed a significant relief in pain over 26 weeks of follow-up after autologous blood injection in lateral epicondylosis of the elbow.
Seyed et al [18] showed significant improvement in VAS score and Modified Mayo Clinic performance index score after autologous blood injection in lateral epicondylosis at 8 weeks of follow-up.
The study conducted by Zeisiget al [14] in 2006 also showed that pain was significantly relieved in 11/13 elbows after injection with polidocanol over 3 months of follow-up.
Zeisig et al [8] in 2008 conducted a prospective, randomized double blind trial comparing injections of polidocanol and lidocaine with epinephrine in 34 patients. At 3 months and 12 months of follow-up, there were no significant differences in satisfaction, pain or grip strength between the groups, although all patients had improved pain and grip strength compared with baseline.
In the current study, Autologous blood injection independently gave a significant pain relief and significantly downstaged the disease symptom in the short term follow-up over a period of 12 weeks as mean reduction observed in the values of Nirschl score at 6 weeks and 12 weeks of follow up after local autologous blood injection was significant. (p value=0.001). Polidocanol injection independently gave a significant pain relief and significantly downstaged the disease symptom in the short term follow-up over a period of 12 weeks as mean reduction observed in the values of Nirschl score at 6 weeks and 12 weeks of follow up after local polidocanol injection was significant.(p value=0.001).

Strength and limitations of the study

The strength of the current study is prospective randomized controlled study, however the limitation of the study is large attrition which was due to the migratory population coming to our hospital who go back to their distant native places after intervention.

Conclusion

Both autologous blood injection and polidocanol injection significantly improved the clinical and functional outcomes at 6 weeks and 12 weeks of follow-upindividuallu but between the two no single modality was better than the other.

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