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Original research article

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 affects nearly 2% of general population. It's etiology and management still remain controversial but is more commonly seen in daily wage workers. Numerous researches have showcased benefits with local injection of autologous blood and polidocanol individually however, there is inadequate research to compare the outcome of local autologous blood injection and polidocanol injection. This was a comparative study for assessing the clinical and functional outcomes of local autologous blood versus polidocanol injection using Nirschl score for treatment of lateral epicondylosis of elbow.

Materials and Methods: 60 patients (age group-18 to 60 years) with lateral epicondylosis of elbow for >3 months were chosen and randomized into 2 groups. 30 patients were injected with autologous blood and 30 patients with polidocanol after Nirschl staging. Patients were assessed clinically at 6 & 12 weeks after the treatment and were again staged by Nirschl staging on both the visits.

Results: 60 patients successfully completed 12 weeks follow-up and were included in the analysis. It was observed that clinically patients in group 1 had better Nirschl scores at 6 and 12 weeks. 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 ± 1.281 at 6 weeks and 12 weeks follow-up respectively). More symptomatic improvement was noted in group I (18/30) than in group 2 (21/30).

However the difference in the mean values of Nirschl score between the groups was not statistically significant. (p value =0.342).

Conclusion: Although Autologous blood injection showed a better clinical outcome in comparison to Polidocanol injection, the difference was not statistically significant.

Keywords: Lateral epicondylosis, autologous blood injection, polidocanol injection

Introduction

Lateral epicondylosis of elbow is a chronic degenerative condition of the tendon rather than an inflammatory state that affects the common extensor origin of the forearm [3]. 2% of the general population are affected by this condition [1, 2, 3, 4].

Though lateral epicondylosis is usually self-limiting various treatment strategies have been devised and employed to improve short term results [2].

Unfortunately there are only a handful treatment modalities that are effective and there is lack of research

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in proving ones efficacy over the other. Absence of confirmation is due to lateral epicondylosis being self-limiting with follow-up period of 12 months or less, Several factors affect the outcome and cause inadequate pathophysiological data [5, 6]. In spite of lateral epicondylosis being so common, a constant endeavour is on to find the best treatment modality for it [7].

Researches have shown advantages with local autologous blood injection and polidocanol injection [1, 3, 8]. As per our analysis, there is no study comparing the treatment modalities clinical and functional results of lateral epicondylosis by autologous blood versus polidocanol. The present this study is to compare the clinical and functional outcomes in lateral epicondylosis of elbow in adults (age 18-60 years) treated by local injection of autologous blood or polidocanol.

Materials and Methods

60 patients affected by lateral epicondylosis of elbow presenting at out tertiary centre hospital in the out-patient department from the period of December of 2013 to April of 2015 were enrolled for the study. The patients with age group above 18 or below 60 years of either sex, not having received previous treatment for pain on the lateral aspect of elbow >3 months were included in the study. The patients excluded were those having confounding factors such as history of fracture or previous surgeries around the involved elbow, any local sign of infection at the proposed injection site, polyarthralgia, acute thromboembolic disease and known allergy to polidocanol. Detailed history was taken from the patients followed by clinical assessment for pain on the lateral aspect of the elbow during daily activities for a period of more than 3 months and/or lateral epicondyle tenderness during resisted dorsiflexion of the wrist with extended elbow. X rays of involved elbow in standard AP and lateral views were taken to eliminate any other etiology of elbow pain. All patients fulfilling the inclusion criteria were recruited for study after having taken their informed written consent. Recruited patients were randomized into two groups as per plan generated by www.randomization.com. Patient details and follow-up were recorded in a predesigned case proforma.

Group I (Local injection with autologous blood)

After having the patient staged according to Nirschl staging, 1 ml of 2% lignocaine was injected locally at point of maximum tenderness of lateral epicondyle of humerus. After 5 minutes, patient was injected with 2 ml of autologous venous blood drawn from contralateral elbow antecubital fossa.

Group II (Local injection with polidocanol)

After having the patient staged according to Nirschl staging, patient was injected with 0.5 to 1 ml of polidocanol by 22 gauge needle.

Post injection, patient was allowed to perform routine activities. Patient was advised to take analgesics only if needed and avoid actions requiring repetitive wrist and elbow movements during initial 3 weeks post injection. Passive stretches of the forearms extensor muscle group were started as pain subsided. Patients were clinically assessed at 6 weeks & 12 weeks post injection using Nirschl score. (Table 1)

On each follow-up visit, patients were advised to continue gentle passive stretch exercises of forearm extensor compartment.

Statistical analysis

The minimum sample size for this study was 30 in each group 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 (Autologous blood/Polidocanol injection) and at 6 weeks and 12 weeks of follow-up in either group.

Table 1: Mean age of patients

	N	Minimum	Maximum	Mean	Std. Deviation
Age	60 patients	22 years	58 years	39.48 years	7.984
Valid N (list wise)	60				

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Table 2: Sex distribution of patients

Randomized Group	Frequency	Percent	Valid Percent	Cumulative Percent
1	21 males	35%	35%	35%
2	39 females	65%	65%	100%
Total	60 patients	100%	100.0	

Table 3: Age statistics of patients

Random grp	N	Mean	Std. Deviation	Std. Error Mean
1	30 patients	39.70 years	8.163	1.490
2	30 patients	39.27 years	7.935	1.449

Table 4: Random group sex cross tabulation count

		Sex		Total
		Male	Female	
Random grp	1	12 patients	18 patients	30 patients
	2	9 patients	21 patients	30 patients
Total		21 male patients	39 female patients	60 patients

Results

60 patients of lateral epicondylosis of the elbow were enrolled in this study and successfully completed 12 weeks follow-up and were included in the final analysis.

Out of these 60 patients, 30 patients (Average age 39.71 years with range 22-58 years, 30% males and 70% females) received local autologous blood injection and 30 patients (Average age 37.93 years with range 27-45 years, 40% males and 60% females) received local polidocanol injection. Thus there was no significant difference in mean age between the groups (p value=0.098).

Female patients dominated the study in both the groups with 70% of female patients (21/30) in group I and 60% female patients (18/30) in group II. There was no significant difference in sex distribution between the groups (p value=0.714).

Clinical and functional outcomes

Out of total 60 patients, 3 patients (case no. 18, 19 and 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 and 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

There was a significant mean decrease in Nirschl score at 6 and 12 weeks of follow up in patients receiving autologous blood (p value = 0.001). (Table 2)

Group II

There was a significant mean decrease in Nirschl score at 6 and 12 weeks of follow up in patients receiving polidocanol injection (p value=0.001). (Table 2)

It was concluded that both autologous blood and polidocanol injections provided significant pain relief and reduced the symptomatology of lateral epicondylosis of elbow in both groups of patients at 6 and 12 weeks of follow up.

Table 5: Mean Nirschl scores at 6 and 12 weeks of follow up

Group	n	Pre-intervention	At 6 weeks of follow-up	At 12 weeks of follow-up	p-value	Significance between time points
I	30	6.07 $\pm$0.907	4.27$\pm$1.143	4.03$\pm$1.326	<0.001	Significant
II	30	5.93 $\pm$0.785	4.60$\pm$1.163	4.53$\pm$1.137	<0.001	Significant

n=Number of patients

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Table 6: Comparison of mean Nirschl scores of two groups at 6 and 12 weeks of follow up

	Group 1	Group 2	p-value	Significance between groups
	(n=30)	(n=30)		NS
6 weeks	4.27 ±1.143	4.60 ±1.163	0.471	NS
12 weeks	4.03 ±1.326	4.53 ±1.137	0.942	NS

NS=Not Significant n=Number of patients

Between group analysis

The two groups were compared and their respective Nirschl scores were plotted on chart in which it was clearly observed that there was a downward trend over a period of 12 weeks.

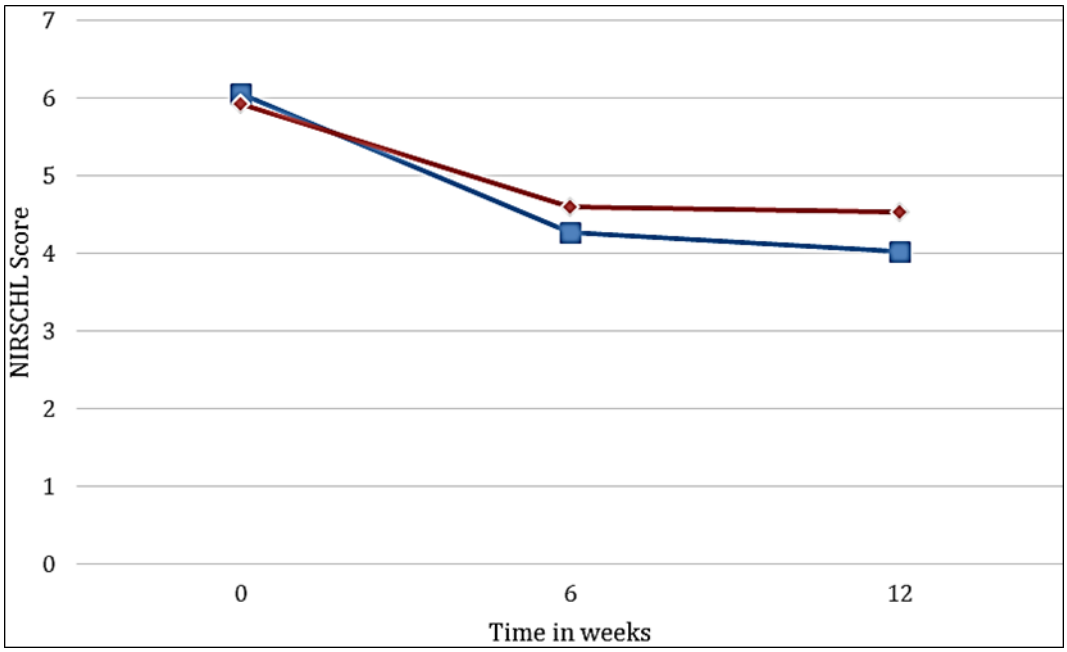

Chart 1: Chart comparing the Nirschl values of Group 1 and group 2 at 6 and 12 weeks of follow up

The two groups were statistically compared and it was observed that the patients of group 1 demonstrated a lower mean value of Nirschl score than the patients of group 2 at the end of 6 and 12 weeks of follow up period. But the differences between the two means was not statistically significant. (p value = 0.001) (Table 3)

Discussion

Local injectable treatment is an attractive and promising modality for managing pain due to lateral epicondylosis of elbow as compared to other conservative and surgical strategies albeit which injection is to be instituted is not confirmed [3].

The mean age in our study was 39.7 years in group I and 39.27 years in group II which is consistent with the literature [8, 9, 10, 12, 13, 14, 15, 16, 17].

Studies conducted by Edwards *et al.* [11], Gani *et al.* [15] and Jindal *et al.* [9] on lateral epicondylosis of elbow also used the Nirschl scoring system.

Jindal *et al.* [9] through a Randomized controlled trial in 2013 on 25 patients per group compared autologous blood and steroid injection in lateral epicondylosis. An improvement in Nirschl score mean 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 differences in mean score of the Nirschl scale in this study was significant. Autologous blood group had a mean age of 39.04 years and mean age in steroid group was 37.32 years.

A Prospective case series was conducted by Edwards *et al.* [11] in 2003 and discovered that after having injected patients elbows with one to three injections of autologous blood, Nirschl scores decreased with complete pain subsidence at an average follow-up of 9.5 months in 79% of patients.

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A Prospective case series was conducted by Gani *et al*. [16] in 2007 in which autologous blood injection was administered to patients elbows affected with lateral epicondylosis. Nirschl score showed an improvement (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.

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

A Randomized controlled trial was conducted by Ozturan *et al*. [12] comparing steroidal injection and autologous blood injection and ESWT (Extra-corporeal shock wave therapy) in 2010. It was observed that steroidal injections were better at short term of 4 weeks of follow-up but autologous blood and ESWT (Extra-corporeal shock wave therapy) were better at 1 year of follow-up with the mean age of patients in this study being 45 years.

VAS and DASH scores were better after autologous blood injection in lateral epicondylosis over 6 months of follow-up period in a study conducted by Wolf *et al*. [10].

A study conducted by Cornell *et al*. [15] showed alleviation of pain after autologous blood injection in lateral epicondylosis of the elbow over a 26 week period of follow-up.

A study conducted by Seyed *et al*. [18] which assessed VAS score and Modified Mayo Clinic performance index score after autologous blood injection in lateral epicondylosis at 8 weeks of follow-up also showed desirable results in pain reduction.

Zeisig *et al*. [14] conducted a study in 2006 also showed pain relief in 11 out of 13 elbows after polidocanol injection over 3 month of follow-up period.

Zeisig *et al*. [8] also conducted a prospective, randomized double blind trial in 2008 where comparison between injections of polidocanol and lidocaine with epinephrine was done in 34 patients. It was observed that there was no significant difference in satisfaction, pain or grip strength between the groups at a follow up period of 3 and 12 months respectively, albeit all patients had reduced pain and better grip strength as compared to initial symptoms.

In the current study, autologous blood injection was shown to alleviate pain and reduced the symptoms in the short term follow-up period of 12 weeks and significant reduction in Nirschl mean scores were observed at 6 weeks and 12 weeks. (p value=0.001). Polidocanol injection also reduced pain and downscaled the symptoms and significant reduction in the mean scores were noted at follow up periods of 6 and 12 weeks. (p value=0.001).

Conclusion

The present randomized control study shows that both autologous blood injection and polidocanol injection efficiently improved the clinical and functional outcomes at 6 weeks and 12 weeks of follow-up, albeit no single treatment was better than the other.

References

1. Nirschl RP, Alvarado GJ. In: Morrey BF, Sanchez-Sotelo J, editors. The Elbow and Its Disorders, 4th ed. Philadelphia: Saunders Elsevier; c2009.
2. Sayegh ET, Strauch RJ. Does nonsurgical treatment improve longitudinal outcomes of lateral epicondylitis over no treatment? A meta-analysis. Clin. Orthop. Relat. Res. 2015 Mar;473(3):1093-107.
3. Judson CH, Wolf JM. Lateral epicondylitis: review of injection therapies. Orthop Clin North Am. 2013 Oct;44(4):615-23.
4. Chop WM Jr. Tennis elbow. Postgrad Med. 1989 Oct;86(5):301-4, 307-8.
5. Hong QN, Durand MJ, Loisel P. Treatment of lateral epicondylitis: where is the evidence? Joint Bone Spine. 2004 Sep;71(5):369-73.
6. Almekinders LC, Temple JD. Etiology, diagnosis, and treatment of tendonitis: an analysis of the literature. Med Sci. Sports Exerc. 1998 Aug;30(8):1183-90.
7. Calfee RP, Patel A, Da Silva MF, Akelman E. Management of lateral epicondylitis: current concepts. J Am Acad Orthop Surg. 2008 Jan;16(1):19-29.
8. Zeisig E, Fahlström M, Ohberg L, Alfredson H. Pain relief after intratendinous injections in patients with tennis elbow: results of a randomised study. Br J Sports Med. 2008 Apr;42(4):267-71.

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9. Jindal N, Gaury Y, Banshiwal RC, Lamoria R, Bachhal V. Comparison of short term results of single injection of autologous blood and steroid injection in tennis elbow: a prospective study. J Orthop Surg Res. 2013 Apr 27;8:10.
10. Wolf JM, Ozer K, Scott F, Gordon MJ, Williams AE. Comparison of autologous blood, corticosteroid, and saline injection in the treatment of lateral epicondylitis: a prospective, randomized, controlled multicenter study. J Hand Surg Am. 2011 Aug;36(8):1269-72.
11. Edwards SG, Calandruccio JH. Autologous blood injections for refractory lateral epicondylitis. J Hand Surg. Am. 2003 Mar;28(2):272-8.
12. Ozturan KE, Yucel I, Cakici H, Guven M, Sungur I. Autologous blood and corticosteroid injection and extracoporeal shock wave therapy in the treatment of lateral epicondylitis. Orthopedics. 2010 Feb;33(2):84-91.
13. Kazemi M, Azma K, Tavana B, Rezaiee Moghaddam F, Panahi A. Autologous blood versus corticosteroid local injection in the short-term treatment of lateral elbow tendinopathy: a randomized clinical trial of efficacy. Am J Phys Med Rehabil. 2010 Aug;89(8):660-7.
14. Zeisig E, Ohberg L, Alfredson H. Sclerosing polidocanol injections in chronic painful tennis elbow-promising results in a pilot study. Knee Surg. Sports Traumatol Arthrosc. 2006 Nov;14(11):1218-24.
15. Connell DA, Ali KE, Ahmad M, Lambert S, Corbett S, Curtis M. Ultrasound-guided autologous blood injection for tennis elbow. Skeletal Radiol. 2006 Jun;35(6):371-7.
16. Gani NU, Butt MF, Dhar SA, *et al*. Autologous blood injection in the treatment of Refractory Tennis Elbow. The Internet Journal of Orthopaedic Surgery, 2007.
17. Creaney L, Wallace A, Curtis M, Connell D. Growth factor-based therapies provide additional benefit beyond physical therapy in resistant elbow tendinopathy: a prospective, single-blind, randomised trial of autologous blood injections versus platelet-rich plasma injections. Br J Sports Med. 2011 Sep;45(12):966-71.
18. Raeissadat SA, Sedighipour L, Rayegani SM, Bahrami MH, Bayat M, Rahimi R. Effect of Platelet-Rich Plasma (PRP) versus Autologous Whole Blood on Pain and Function Improvement in Tennis Elbow: A Randomized Clinical Trial. Pain Res Treat, 2014, 191-525.