

Original Research Article

Comparison between prolotherapy using 25% dextrose versus extracorporeal shock wave therapy in the management of pain and improvement of functional outcome in patients suffering from chronic lateral epicondylitis: a randomized controlled trial

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ABSTRACT

Background: Lateral epicondylitis is a tendinopathy characterized by pain around the lateral aspect of the elbow occurring more frequently in nonathletes than athletes significantly affecting the patient's life in terms of the quantity and quality of work done. In resistant cases of tennis elbow, a number of treatment options have been tried including extracorporeal shockwave therapy, autologous blood injections and surgery as last resort but none of them has proved to be superior over another. Recent studies show that 25% dextrose prolotherapy which induces an inflammatory reaction at site of administration would be a better treatment option in resistant cases.

Methods: A prospective randomized controlled trial was done in Department of Physical Medicine & Rehabilitation, Regional Institute of Medical Sciences, Imphal to compare the effectiveness of 25% dextrose prolotherapy injection and extracorporeal shockwave therapy in management of pain and improvement of functional outcome in patients suffering from chronic lateral epicondylitis.

Results: The outcome variables VAS for pain and Grip strength for function were measured at baseline, 1 month, 3 months and 6months. Data collected were analysed using SPSS version 21. For analytical purpose, description statistics like mean and standard deviation were used. Statistical tests like t-test, Chi square test, Fisher's exact test were used for intra group and inter group analysis. P-value <0.05 was taken as significant. In study group 2ml of 25% dextrose mixed with 2% lignocaine (0.5ml) was given to the affected lateral epicondyle. In control group, weekly sessions of single sitting ESWT was given to the lateral epicondyle for 3 consecutive weeks. In the follow up assessment at 1 month, 3 months and 6 months, there was significant improvement in mean score of VAS and Grip Strength scores in both the groups ($p < 0.05$). When both the groups were compared with each other, study group showed a better improvement and was found to be significantly more effective than shockwave therapy group in reducing pain and improvement of functional outcome in chronic lateral epicondylitis ($p = 0.001$).

Conclusions: Prolotherapy may be considered as a novel alternative conservative management before opting for surgery in resistant cases of lateral epicondylitis.

Keywords: Prolotherapy, ESWT, Gripstrength, Lateral epicondylitis

INTRODUCTION

Lateral epicondylitis or tennis elbow is a disease characterized by pain over lateral aspect of the elbow. The disease is generally characterized by pain located over the origin of Extensor Carpi Radialis Brevis (ECRB) and tenderness over the lateral epicondyle. The vulnerability of ECRB in lateral epicondylitis is mainly attributed to the anatomical location. The origin of ECRB on the humerus is slightly medial and superior to the outer edge of capitellum. During extension of the elbow, the undersurface of ECRB rubs against lateral edge of the capitellum, together with the ECRL (extensor carpi radialis longus) tendon compressing the ECRB tendon against the underlying bone. This causes abrasion of the tissue leading to ECRB tendinosis. The overall incidence of this disease is about 3-4 persons /year. The disease is mainly caused by repetitive movements of the involved muscle particularly in the working generation of people. A frequent consequence of this disease is absence from work for several weeks months or year. Lateral epicondylitis can cause a significant weakness in strength of grip when elbow is kept in extension.¹ The peak incidence is generally seen in the 5th decade of life and incidence among both male and female is similar. Local injury, overuse, aging, obesity, smoking, physical loading activities like playing backhand shot in tennis, are among the various causes for lateral epicondylitis.² The main pathogenesis leading to lateral epicondylitis is mainly the overuse of extensor muscles leading to degenerative pathology of the involved tendons.³ The diagnosis of tennis elbow is clinical. It is detected by localizing tenderness at origin of extensor carpi radialis brevis (ECRB). Tenderness is present over lateral epicondyle approximately 5mm distal to midpoint of lateral epicondyle. Pain is usually exacerbated by dorsiflexion of wrist against resistance and dorsiflexion of wrist against resistance and forearm supination and on grasping object.⁴

Chronic lateral epicondylitis will be diagnosed if there is persistent pain and tenderness on or near lateral epicondyle despite all conservative treatments spanning for a minimum period of 6 months along with 2 out of 3 pain provocative test positive. The tests are:

Gripping test, Cozen's test, Mills test.

Conservative treatments like – Rest, NSAIDS, Stretching, Splinting, local injection of steroid, have been reported with varying result. But no one is being recognized as superior.⁵

Surgery (open, percutaneous or arthroscopic release of the extensor origin, debridement and denervation of the lateral epicondyle) remains a last option for the treatment of tennis elbow because this has considerable cost, complication and modest success in treating chronic recalcitrant tennis elbow. There is a clear need for effective alternative conservative therapies and thus there

has been a recent push to evaluate the possibility of prolotherapy and other biologics like autologous whole blood, platelet rich plasma, bone marrow aspirate (BMA) that may allow for healing of the chronic degeneration within the extensor tendons.⁶

The objective of the study was to compare the efficacy of prolotherapy using 25% dextrose versus extracorporeal shock wave therapy in the management of pain and improvement of functional outcome in patients suffering from chronic lateral epicondylitis.

METHODS

Study design

Randomized controlled trial

Setting

Department of Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences, Imphal, Manipur.

Duration of study

Two years (August 2018 to July 2020).

Study population

All patients suffering from lateral epicondylitis attending PMR OPD, Regional Institute of Medical Sciences, Imphal during study period.

Inclusion and Exclusion criteria for Participation.

Inclusion criteria

Patients diagnosed with lateral epicondylitis fulfilling following criteria was included in this study

Age between 30-50 years, Duration of symptoms for at least 6 months, Failed conservative treatment, Willingness to comply with treatment and follow-up assessment.

Exclusion criteria

Duration of symptoms less than 6 months, History of previous surgery in the same tendon, Implanted hardware adjacent to the target treatment region, Abnormal radiographic findings like Osteophytes, Calcification, or Exostosis, Pregnancy, Diabetes, Cancer.

Sample size

Total sample size is 42 in each group. Sample size is calculated based on formula.

n = sample size

$$n = (\sigma_1^2 + \sigma_2^2) \times \frac{[z_{1-\beta} + z_{1-\frac{\alpha}{2}}]^2}{(m_1 - m_2)^2}$$

$$n = (1.24^2 + 1.31^2) \times \frac{[1.96 + 1.28]^2}{(5.58 - 4.63)^2}$$

$$n = 3.2537 \times \frac{10.516}{0.9025} = 37.89 \approx 38$$

Considering 10% drop out rate, sample size = (38+3.8) = 41.8 ≈ 42 patients in each.

Group = Total (42+42) = 84 patients.

Formula source-medical statistics-principles and methods 2nd edition.

The above values were taken from a study conducted by by Koksai et al “Comparison of extracorporeal shock wave therapy in acute and chronic lateral epicondylitis”.⁷

m_1 = mean of the outcome variable in standard group (5.58) based on VAS score

m_2 = mean of the outcome variable in control group (4.63) based on VAS score

σ_1 = standard deviation of the outcome variable in study group (1.24)

σ_2 = standard deviation of outcome variable in control group (1.31)

$z_{1-\beta}$ = function of power of the test =1.28 at 90% power

$z_{1-\alpha/2}$ = function of the confidence level=1.96 at $\alpha=0.05$; 95% confidence interval.

Study variables

Age, Gender, Occupation, Duration of symptoms, Side of affection, Religion.

Study equipment

Swiss Dolorclast Smart product number SN-KC00361 year of manufacture 2015 (ESWT machine).

Outcome measurement tools

The degree of pain and functional outcome will be measured by

Visual Analogue Scale (VAS).

Grip strength Assessment: Hand grip strength can be quantified by measuring amount of static force that the hand can squeeze around a dynamometer. Manual

dynamometer with spring mechanism was used for grip strength measurement. The minimum reading was 0 and maximum recordable value was 22. The force was measured in kilogram. The patient squeezed the dynamometer with maximum isometric effort which was maintained 5 seconds. The procedure was repeated with a gap of 15 seconds. The results were calculated as the average of both the values.

Procedures

Study group: Prolotherapy injections using dextrose 25% solution was prepared by the injector at the time of procedure. Tenderness at the lateral epicondyle was confirmed by palpation. Patient was positioned in supine lying with elbow flexed around 10 degree.

The area was then cleaned with betadine solution and isopropyl alcohol to maintain strict aseptic environment. After that 2% lignocaine (0.5ml) used as local anaesthetic mixed with 2ml of 25% dextrose solution. Then 0.5ml of the prepared solution will be injected onto the lateral epicondyle. Then up to 2 ml of the solution was “peppered” on bone along a short segment of the tendon at the areas of palpated tenderness. The patients were advised to take rest for 2-3 days post-procedure and progressive resumption of routine activity over one month.

Control group: In this group patients received a total 3 sessions of shock wave therapy at weekly interval for 3 weeks. Patient was positioned in supine lying with elbow flexed around 10 to 20 degree. During every session by using Swiss Dolorclast Smart product number SN-KC00361, shock wave therapy was applied on painful points (10HZ,1.9BAR, 2000shock) by using electric gun with a R10 applicator tip and a skin protective gel.

Follow up was done for both the group at the end of 1 month, after 3 months and after 6 months. All the patients were advised to reduce physical activities and take rest as much as possible. Patients of both the groups received analgesic Tab Tramadol 50mg as when required.

Statistical analysis

Data was collected in a pre-tested proforma. Analysis was done using Statistical Package for the Social Sciences (SPSS) version 21.0, Armonk, NY: IBM Corp. Categorical variables like gender, side of affection and age group were expressed as number of patients and percentage of patients and compared across the two group using Chi- Square test.

For occupation and religion as cell sample was very small Fisher Exact test was used. Continuous variables like duration of symptoms, VAS score, Grip Strength score were expressed as Mean±Standard Deviation (SD) and compared across the two group using independent t test, within the group comparison was done by paired t test. P value <0.05 was taken as significant.

RESULTS

Table 1 shows the mean VAS score of study and control groups were 7.57±0.67 and 7.57±0.50 respectively. The Grip Strength score of study and control groups were 10.00±0.99 and 9.69±0.84 respectively. There was, no statistical significant difference between the two groups

at the baseline in terms of VAS and Grip strength score (p>0.05).

Table 2 shows the mean scores of VAS and Grip Strength at baseline and 1 month. The table shows significant improvement in both mean VAS scores and Grip Strength scores at 1 month in both the groups (p<0.05).

Table 1: Baseline characters of the study group and control group.

Characteristics		Study group N (%)	Control group N (%)	P value
Age (in year)	30-40	16 (38.1)	12 (28.6)	0.505*
	41-50	26 (61.9)	30 (71.4)	
Gender	Female	22 (52.4)	28 (66.7)	0.182*
	Male	20 (47.6)	14 (33.3)	
Occupation	House wife	20 (47.6)	23 (54.8)	0.408**
	Businessman	3 (7.1)	1 (2.4)	
	Teacher	8 (19)	12 (28.6)	
	Policeman	5 (11.9)	3 (7.1)	
	Carpenter	3 (7.1)	0 (0)	
Religion	Driver	3 (7.1)	3 (7.1)	0.109**
	Hindu	36 (85.7)	40 (95.2)	
	Muslim	6 (14.3)	1 (2.4)	
Side of affection	Christian	0 (0)	1 (2.4)	1.000*
	Right	20 (47.6)	20 (47.6)	
	Left	22 (52.4)	22 (52.4)	
Duration (in months) (Mean ± SD)		7.43±1.064	7.64±1.08	0.362#
VAS (mean ± SD)		7.57±0.67	7.57±0.50	1.000#
Grip strength in kg (Mean ± SD)		10.00±0.99	9.69±0.84	0.126#

Independent t test, ** Fisher exact test, * Chi square test

Table 2: Comparison between scores of outcome measures at baseline and 1 month.

Parameter	Group	Baseline	1 month	P value*
VAS (Mean ±SD)	Study group	7.57±0.67	5.36±0.82	<0.001
	Control group	7.57±0.50	6.26±0.77	<0.001
Grip strength (Mean ±SD)	Study group	10.00±0.99	11.99±0.93	<0.001
	Control group	9.69±0.84	10.74±0.88	<0.001

*Paired t test, P value <0.05 taken as significant

Table 3: Comparison between scores of outcome measures at baseline and 3 months.

Parameter	Group	Baseline	3 months	P value*
VAS (mean ±SD)	Study group	7.57±0.67	3.17±1.03	<0.001
	Control group	7.57±0.50	4.45±1.27	<0.001
Grip strength (Mean±SD)	Study group	10.00±0.99	13.84±0.87	<0.001
	Control group	9.69±0.84	11.83±0.96	<0.001

*Paired t test, p value <0.05 taken as significant

Table 3 shows the mean scores VAS and Grip Strength at baseline and 3 months. The table shows significant improvement in both mean VAS scores and Grip strength scores at 3 months in both the groups.(p<0.05).

improvement in both mean VAS scores and Grip strength scores at 6 months in both the groups (p<0.05).

Table 4 shows the mean scores of VAS and Grip strength at baseline and 6 months. This table shows significant

Table 5 shows the comparison of mean VAS score between the two groups at different follow up periods. Study group shows significant reduction in VAS score over study period and achieved the difference of VAS score at 6 months at 6.119 when compared to only 4.500

in control group, implying the prolotherapy is having better outcome than ESWT.

Table 6 shows the comparison of mean Grip Strength scores between the two groups at different follow up periods. Study group shows significant improvement of

Grip Strength score over study period and achieved the difference of Grip strength at 6 months at 5.413 when compared to only 3.425 in control group, implying the prolotherapy is having better outcome than ESWT.

Table 4: Comparison between scores of outcome measures at baseline and 6 months.

Parameter	Group	Baseline	6 months	P value*
VAS (Mean± SD)	Study group	7.57±0.67	1.45±0.59	<0.001
	Control group	7.57±0.50	3.07±0.92	<0.001
Grip strength (Mean± SD)	Study group	10.00±0.99	15.44±0.65	<0.001
	Control group	9.69±0.84	13.1±0.84	<0.001

*Paired t test, p value <0.05 taken as significant

Table 5: Comparison between mean score for VAS between the two groups.

VAS Score (Mean±SD)	Intervention given		Total	P value
	Study group	Control group		
Baseline	7.57±0.67	7.57±0.50	7.57±0.59	1.000
After 1 month	5.36±0.82	6.26±0.77	5.81±0.91	<0.001**
After 3 months	3.17±1.03	4.45±1.27	3.81±1.32	<0.001**
After 6 months	1.45±0.59	3.07±0.92	2.26±1.12	<0.001**

Independent t test, ** strongly significant p value, p value <0.05 taken as significant

Table 6: Comparison between scores for Grip Strength between the two groups.

Grip strength (Mean±SD)	Intervention given		Total	P value*
	Study group	Control group		
Baseline	10.00±0.99	9.69±0.84	9.84±0.93	0.126
After 1 month	11.99±0.93	10.74±0.88	11.36±1.10	<0.001**
After 3 months	13.84±0.87	11.83±0.96	12.83±1.36	<0.001**
After 6 months	15.44±0.65	13.1±0.84	14.27±1.39	<0.001**

Independent-t test, ** strongly significant p value, p value <0.05 taken as significant

DISCUSSION

Lateral epicondylitis is one of the most commonly encountered tendinopathy we come across in our day to day life. Various conservative treatment strategies had been used in the treatment of lateral epicondylitis. But none of the conservative treatment have been proved to be adequate in treating lateral epicondylitis. Surgical treatment is the last option and it is expensive and also associated with morbidity and complications. Fear and ignorance about surgical procedure is a big issue in the minds of the patients ultimately leading to refusal of surgery. As a result there is utmost need for effective alternative conservative therapies. Prolotherapy had shown promising result in the treatment of tendinopathy. According to a study conducted by Rabago D et al inoculation of dextrose prolotherapy proved to be an effective treatment option for patients suffering from chronic lateral epicondylitis.⁸

In study group, the mean VAS score improved from 7.5±0.6 at baseline to 5.3±0.8 at 1 month, 3.1±1.03 at 3

months and 1.4±0.5 at 6 months follow up (p<0.05) and Grip Strength improved from 10.0±0.9 at baseline to 11.9±0.9 at 1month, 13.8±0.8 at 3 months and 15.4±0.6 at 6 months follow up (p<0.05). Grip strength was measured in kilogram (kg) and expressed as mean ±standard deviation. In a study conducted by Singh et al, they found similar statistically significant improvement of VAS and PRTEE score at 4 weeks and 12 weeks follow up.⁹ In their study, follow up was done at 4 weeks and 12 weeks and still the improvement in pain was evident as early as 4th week. Hence the follow up period was fixed at 1 month (approximately 4weeks) to observe the optimal effect and at 3 months (approximately 12 weeks) and 6months (approximately 24 weeks) to study the long term outcome. In control group the mean VAS score improved from 7.5±0.5 at baseline to 6.2±0.7 at 1 month, 4.4±1.2 at 3 months and 3.07±0.9 at 6 months follow up (p<0.05) and the mean Grip Strength improved from 9.6±0.8 at baseline to 10.74±0.88 at 1 month, 11.83±0.96 at 3 months and 13.1±0.8 at 6 months follow up (p<0.05). In a study conducted by Yang TH et al similar statistically significant improvement in VAS and

Grip strength score was found at 12 weeks and 24 weeks which proves that ESWT can improve grip strength in patients suffering from lateral epicondylitis and hence justify the present study.¹⁰

Intra- and Inter group analysis was performed and study group showed significant reduction in VAS score over study period and achieved the difference of VAS score at 6 months at 6.1 when compared to only 4.5 in control group whereas in Grip strength study group showed significant improvement of Grip Strength score over study period and achieved the difference of Grip strength at 6 months at 5.4 when compared to 3.4 in control group.

From the above comparison it was clear that both prolotherapy and ESWT are effective in the management of pain (in terms of VAS) and improvement of functional outcome (in terms of Grip Strength), but the improvement shown by prolotherapy was better when compared to ESWT.

CONCLUSION

Single injection of 25% dextrose prolotherapy is more effective in reducing pain and improving functional outcome in chronic lateral epicondylitis as compared to extracorporeal shockwave therapy and may be considered as a novel alternative for surgery in resistant cases.

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