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Original Research Article

Comparison between prolozone therapy and extracorporeal shockwave therapy in management of pain and function in resistant cases of lateral epicondylitis: a randomised controlled trial

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ABSTRACT

Background: Lateral epicondylitis also known as the tennis elbow is a painful condition of the elbow caused by overuse. The disease imparts significant disability to those affected in terms of the quantity and quality of work done.
Methods: A randomised controlled trial was conducted in the Department of Physical Medicine and Rehabilitation, RIMS, Imphal for a period of 1 year from February 2017 to January 2018. Eighty-four patients with resistant lateral epicondylitis recruited were divided into 2 groups- group A received Prolozone injection while group B underwent Extracorporeal Shockwave Therapy (ESWT).
Results: Assessments of VAS (Visual Analog Scale) and PRTEE (Patient Rated Tennis Elbow Evaluation) were done at 8 weeks and 24 weeks. The mean VAS score in Prolozone group improved from 7.22±0.89 to 4.04±1.01 at 8 weeks to 1.67±0.70 at end of 24 weeks. In ESWT group, mean VAS score improved to 3.91±0.72 at 8 weeks and reduced to 2.3±0.68 at end of 24 weeks. PRTEE improved significantly in both the groups, from 85.33±3.29 to 24.87±2.10 in Prolozone group, and from 85.17±2.83 to 41.89±3.17 in ESWT group.
Conclusions: The improvement in pain and disability is better in prolozone group than ESWT ($p<0.05$) in chronic lateral epicondylitis.

Keywords: Extracorporeal shockwave therapy, Lateral epicondylitis, Prolozone

INTRODUCTION

Lateral epicondylitis also known as the tennis elbow is a term used to describe myriad of symptoms around the lateral aspect of the elbow which occurs more frequently in non-athletes than athletes.[1] The disorder arises as a result of repetitive movements of the involved muscles particularly in the working age group. It has been found to occur in approximately 1-3 % of people in studied populations. The peak incidence is in the early fifth decade and a nearly equal gender incidence is seen. The diagnosis of tennis elbow is usually made clinically by localizing discomfort at the origin of the extensor carpi radialis brevis (ECRB). ECRB tendon is the most commonly involved structure in tennis elbow. This is explained by the 'anatomic vulnerability of ECRB origin to attrition' theory which mentions that ECRB originates from the superomedial part of outer edge of capitellum. During extension, the undersurface of ECRB rubs against the lateral edge of capitellum, together with the Extensor Carpi Radialis Longus (ECRL) compressing the ECRB against the underlying bone. This causes abrasion of tissues leading to ECRB tendinosis.[2] Tenderness is present over the lateral epicondyle approximately 5 mm

distal and anterior to the midpoint of the condyle. Pain usually is exacerbated by resisted wrist dorsiflexion and forearm supination and on grasping objects. Resistant lateral epicondylosis is the condition where 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 of 3 pain provocative tests gripping, Cozen's test and Mill's manoeuvre. There are many conservative treatments, including rest, ice, splinting, massage, injection of nonsteroidal anti-inflammatory drugs, counterforce bracing and alteration of tasks performed by the patient.[3,4] Corticosteroid injection has been shown to provide short term relief but relapse rates are high.

Recent literature suggests that corticosteroid injections may actually have deleterious effects after their short-term pain relief. Extracorporeal shock-wave therapy (ESWT) for lateral epicondylosis has been reported to be successful in 48% to 73% of cases recalcitrant to other nonoperative measures. Many mechanisms have been described in explaining shockwave effects, including direct stimulation of healing, neovascularisation, direct suppressive effects on nociceptors and hyperstimulation analgesia by blocking the gate-control mechanism.[5] Recently there has been an overwhelming interest in regenerative medicine for musculoskeletal pain and chronic tendinopathies.

Prolozone therapy is a nonsurgical regenerative injection technique that introduces ozone gas with small amounts of a proliferant solution to the site of painful and degenerated tendon insertions (entheses), joints, ligaments, and in adjacent joint spaces. The most common prolotherapy agent used in clinical practice is dextrose, with concentrations ranging from 12.5% to 25%. Dextrose is considered to be an ideal proliferant because it is water soluble, a normal constituent of blood chemistry, and can be injected safely into multiple areas and in large quantity.

Hypertonic dextrose solutions act by dehydrating cells at the injection site, leading to local tissue trauma, which in turn attracts granulocytes and macrophages and promotes healing. While the ozone gas forms hydrogen peroxide which is the driving molecule for the biological and therapeutic effects. Antioxidant levels decrease and hydrogen peroxide stimulates a shock like effect on the tissues.

This effect results in the stimulation of a variety of defense systems, including primarily antioxidant enzyme expression, leading to increased resistance to the oxidative processes. The first effect of hydrogen peroxide is on the hemoglobin-oxygen dissociation curve which is shifted to the right. With the increase in 2,3-di-phosphoglycerate levels in the erythrocytes, oxygen is released to the tissues much easily. This biochemical mechanism explains the increased tissue partial oxygen pressure during the ozone therapy.[6,7] Thus, it can be considered that ozone could provide new perspectives on the treatment of tendon disorders.

METHODS

A randomised controlled trial was done in the Department of Physical Medicine and Rehabilitation, RIMS, Imphal from February 2017 to January 2018. Eighty-four patients diagnosed with resistant lateral epicondylitis were recruited for the study from the OPD patients. Informed consent was taken from all participants before starting the study.

Diagnosed case of resistant lateral epicondylitis between 18-60 years of age with pain severity of at least 5 based on 10 scale VAS were included in the study. Any recent febrile or infectious disease (systemic and local); history of any malignancy (including hematologic and non-hematologic malignancies); peripheral nerve injuries; systemic illnesses like ischemic heart disease, diabetes, rheumatoid arthritis, hepatitis; any fracture, bony malformation, articular lesions at elbow; history of autoimmune and platelet disorders; treatment with anticoagulant and anti-platelet medications 10 days before injection; pregnancy or breastfeeding; cardiac arrhythmia or a pacemaker; those who received a corticosteroid injection within the previous 8 weeks were excluded from the study.

The 84 participants were randomly assigned to two groups A and B using block randomisation.

Group A (study group) received a single prolozone injection consisting of 2 ml of a proliferant solution and 4 ml of ozone gas. The proliferant solution was prepared by mixing 2.5 ml of 25% Dextrose with 2.5 ml of 1% Lignocaine; while the ozone gas with concentration of 30 µg/ml was prepared by the Medical Ozone Generator Machine (CHEMTRONIS No. MD/OG-60S). The proliferant solution was injected first followed by 4 ml of ozone gas in a separate syringe into the common extensor origin of the affected lateral epicondyle.

Group B received Extracorporeal shockwave therapy, ESWT (SWISS DOLORCLAST® smart) to the affected site using low energy shockwave (energy 2 bar). A total of 2000 impulses at a frequency of 6 Hz was given once weekly for 3 weeks.

Visual Analog Score (VAS) and Patient Rated Tennis Elbow Evaluation (PRTEE) were measured at baseline and follow up assessments were done at 8 and 24 weeks.

VAS (Visual analogue scale)

This is a 10 cm horizontal line on which the patient's pain intensity is represented by a point between the extremes of "no pain at all" and "worst pain imaginable". The patient marks on the line the point that they feel represents their perception of their current state.

The VAS score is determined by measuring in centimetres from the left-hand end of the line to the point that the patient marks.

PRTEE (Patient rated tennis elbow evaluation)

The PRTEE, formerly known as the Patient-Rated Forearm Evaluation Questionnaire (PRFEQ) is a 15-item questionnaire designed to measure forearm pain and disability in patients with lateral epicondylitis.

The PRTEE allows patients to rate their levels of tennis elbow pain and disability from 0 to 10 and consists of 2 subscales:

- Pain subscale (0 = no pain, 10 = worst imaginable)
- Function subscale (0 = no difficulty, 10 = unable to do).

RESULTS

Table 1 shows that there is no statistical differences in the baseline characteristics between the Prolozone and ESWT group.

Table 2 shows the mean improvement in VAS, PRTEE pain subscale, PRTEE function subscale, PRTEE total score were found to be statistically significant ($p<0.05$) in both the Prolozone and ESWT group as tested by using the statistical test repeated measure ANOVA test. The mean VAS score in Prolozone group improved from 7.22±0.89 to 4.04±1.01 at 8 weeks and it further reduced to 1.67±0.70 at end of 24 weeks. In ESWT group, mean VAS score improved to 3.91±0.72 at 8 weeks and reduced to 2.3±0.68 at end of 24 weeks. The improvement in pain and disability is better in prolozone group than ESWT ($p<0.05$).

Table 1: Baseline characteristics of participants.

Characteristics	Prolozone group (n=42)	ESWT group (n= 42)	p-value
Mean age in years (Mean±SD)	39.63±9.09	40.04±7.68	0.251
Gender			
Male	16	15	0.411
Female	22	23	
Side of affection			
Left	4	10	0.494
Right	34	28	
Duration (months)	9.37±2.37	8.91±2.95	0.352
Occupation			
Manual labourers	17	18	
Housewife	15	19	0.312
Sedentary workers	10	5	

$p<0.05$ is taken as significant

Table 2: Mean improvement in VAS and PRTEE during follow up.

Parameter		Group	Baseline	8 weeks	24 weeks	p value*
VAS		Prolozone	7.22±0.89	4.04±1.01	1.67±0.70	0.001
		ESWT	7.35±0.66	3.91±0.72	2.3±0.68	0.001
PRTEE	Pain	Prolozone	45.33±2.45	33.50±3.90	12.37±1.58	0.001
		ESWT	44.26±2.03	30.02±2.16	22.04±2.16	0.001
	Function	Prolozone	40.00±1.78	27.50±4.68	12.50±1.87	0.001
		ESWT	40.91±1.50	23.87±1.79	19.85±1.66	0.001
	Total	Prolozone	85.33±3.29	61.00±4.18	24.87±2.10	0.001
		ESWT	85.17±2.83	53.89±3.26	41.89±3.17	0.001

* ANOVA test; $p<0.05$ is taken as significant

DISCUSSION

Three studies so far have demonstrated that lateral epicondylitis of the elbow is responsive to treatment with dextrose prolotherapy. Scarpone et al, conducted a small double-blind RCT with adults with lateral epicondylosis.[7] The treatment group was injected at 0, 1, and 3 months with 0.72% sodium morrhuate, 10.7% dextrose, 0.29% lidocaine, and 0.04% sensorcaine. The treatment group showed significant improvement in pain levels compared

with patients given saline injection with the same number of needle punctures and volume (91% versus 33%). In addition, extension strength and grip strength was markedly improved in the treatment group as well. Shin et al, studied 84 patients with lateral epicondylitis who were treated with dextrose prolotherapy.[8] The pain score was evaluated by using VAS before treatment and one and six months after the third treatment. Ultrasonography was performed on 49 patients who were suspicious of a tendinous tear. Dextrose prolotherapy decreased VAS from 6.79 to 2.95, which reached statistical significance. Park et al achieved a significant reduction in pain with VAS from baseline patients with lateral epicondylitis as well with treatment of the lateral epicondyle with 15% dextrose.[9] Evidence of tendon healing was observed via ultrasound imaging, manifesting as diffuse fibrillar patterns in previously anechoic lesions and areas of hypervascularity.

The present study shows that both ESWT as well as prolozone provide good results in the improvement of pain and function in resistant cases of lateral epicondylitis. However, prolozone yielded better results than ESWT.

One of the major limitations of the study was that no study was done at tendon level to see the structural changes. Other limitations include blind method of injection and lack of longer follow up.

CONCLUSION

Single injection of prolozone is significantly more effective in reducing pain and disability in resistant lateral epicondylitis at 24 weeks as compared to extracorporeal shockwave therapy and may be considered as a novel alternative to surgery in resistant cases.

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