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RESEARCH ARTICLE

EFFECTIVENESS OF ULTRASOUND GUIDED DEXTROSE PROLOTHERAPY INJECTION IN COMPARISON WITH EXTRACORPOREAL SHOCK WAVE THERAPY ON IMPROVING PAIN AND FUNCTION AMONG ATHLETES WITH ACHILLES TENDINOPATHY: A RANDOMIZED CONTROLLED TRIAL

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Achilles Tendinosis, Dextrose Prolotherapy, Extracorporeal Shock Wave Therapy, Ultrasound, VISA-A, VAS

Abstract

Background: Achilles tendinosis is a chronic, degenerative condition affecting both sedentary individuals and athletes of all abilities, with prevalence in running-based sports particularly high. Pain is considered to be the primary symptom of Achilles tendinosis, to the extent that it is suggested that a patient's symptoms can reflect the severity of the condition. Several treatment modalities such as activity modification, heel lifts, arch supports, stretching exercises, nonsteroidal anti-inflammatories, and eccentric loading are known as standard treatment mostly without proven evidence.

Objectives: To determine the effectiveness of ultrasound guided Dextrose prolotherapy injection in comparison with extracorporeal wave therapy on improving pain and function among athletes with Achilles tendinopathy

Study Design: A Randomized controlled trial

Methods: Fifty eight athletes with achilles tendinopathy meeting the inclusion and exclusion criteria were selected for this study and randomized into 2 treatment groups: dextrose prolotherapy injection under ultrasound guidance (prolotherapy group; n = 29), and 3 sessions of focused extracorporeal shock wave therapy (ESWT group; n = 29). The outcome measures were Victorian Institute of Sports Assessment–Achilles (VISA-A) questionnaire and pain visual analog scale (VAS). Both the groups underwent rehabilitation programs. For descriptive statistics mean, standard deviation and frequency were used. Continuous variables were analysed by student's t-test. Categorical variables were analysed using Chi-square test. Within the group comparison (baseline and follow-up data of each group) was done by Repeated measures ANOVA. Between the groups comparison was analysed using student's t-test. A p-value < 0.05 was taken as significant.

Results: The 2 groups were homogeneous in terms of their baseline characteristics like age, gender, duration of symptoms and side of affection ($p > 0.05$). Within the group comparison showed significant improvement in outcome measures in both the groups at all follow ups ($p = 0.00$). Between the groups analysis found improvement in the VAS and VISA-A scores at all follow ups but the improvement was

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significantly more in the Prolotherapy group in comparison with the ESWT group (p = 0.00).
Conclusion: Ultrasound guided injection of dextrose prolotherapy in combination with eccentric strengthening exercises lead to significant improvement in pain and function over the long term in comparison with focused ESWT among athletes with Achilles tendinosis and thereby enabling faster return to sports.

Introduction:-

Achilles tendinosis is a chronic, degenerative condition affecting both sedentary individuals and athletes of all abilities, with prevalence in running-based sports particularly high[1]. In the general population, the lifetime cumulative incidence of Achilles tendinosis is 5.9% among sedentary people and 50% among elite endurance athletes[2]. The Achilles region thickest and strongest tendon in the human body, is the combined tendon of the gastrocnemius and soleus muscles. The tendon has no synovial sheath but has a posterior peri tendon (also known as paratenon).which is continuous with the perimysium of the muscle and the periosteum of the calcaneus. Anteriorly. the deep surface of the tendon is supported by a fat pad through which the vessels and nerves enter the tendon. The tendon attaches to the inferior half of the calcaneus. The posterosuperior process of the talus approximates the Achilles, often with a bursa between. This area can become symptomatic (insertional Achilles pathology) if a person has a large and rather square-shaped calcaneum[3]. In patients presenting with Achilles region symptoms, the clinician should: distinguish between mid portion Achilles tendinopathy and insertional tendinopathy, as treatment differs slightly but importantly. The site of pain and swelling can help the clinician distinguish mid portion from insertional Achilles pathologies. Injury to the midportion of the Achilles tendon, typically 2–6 cm proximal to its insertion, is more prevalent than tendon pathology found at the insertion and accounts for approximately 66% of all injuries to the Achilles tendon[4].

Pain is considered to be the primary symptom of Achilles tendinosis, to the extent that it is suggested that a patient's symptoms can reflect the severity of the condition[5]. Often patients describe a period of tendon pain that is at least partially resolved through either time or a treatment intervention[6]. Unfortunately, symptoms often return with increased and repeated tensile strain as the athlete returns to the preinjury training regimen. The aetiology of Achilles tendinopathy is associated with several intrinsic and extrinsic factors. The intrinsic factors include impaired blood supply, gastrosoleus dysfunction, age, sex, body weight, metabolic disorders, lateral ankle instability, foot joint hypermobility and foot deformities. The extrinsic factors that might contribute to Achilles tendinopathy are several sport disciplines (volleyball, basketball, and running), changes in training schedules, training errors, past injuries, inadequate footwear, and unsuitable training surfaces[7,8]. Repetitive tendon strain (3–8%) promotes cumulative microtrauma. When the reparative capacity of the tendon is exceeded, the tendon sheath may become inflamed, resulting in oedema, pain, and/or tendon degeneration.

Histologically, tendinopathy is characterized by the absence of inflammatory cells, poor healing, noninflammatory intratendinous collagen degeneration, collagen fibre disorientation and thinning, hypercellularity with high concentrations of glycosaminoglycans and proteoglycans, and neovascularization [9]. Signs of these tissue degeneration are observable sonographically with the use of modern high resolution ultrasound transducers and may include intratendinous tearing, changes in tendon echotexture (structural degeneration), neovessel infiltration, intratendinous calcification, and irregularities to bone cortex at the tendon insertion[10,11].

Several treatment modalities such as activity modification, heel lifts, arch supports, stretching exercises, nonsteroidal anti-inflammatories, and eccentric loading are known as standard treatment mostly without proven evidence. After failed conservative therapy, invasive treatment may be considered. Extracorporeal shock wave therapy (ESWT) has been successfully used in soft-tissue pathologies like lateral epicondylitis, plantar fasciitis, tendinopathy of the shoulder and also in bone and skin disorders. Conclusive evidence recommending ESWT as a treatment for Achilles tendinopathy is still lacking[12].

Prolotherapy involves injecting an irritant, into a joint space, ligament or tendon with the ultimate goal of alleviating pain. The most common prolotherapy agent used in clinical practice is dextrose, with concentrations ranging from 12.5% to 25%.[20] 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. The mechanism of action behind prolotherapy is not completely understood. However, current theory holds that the injected proliferant mimics the natural healing process of the body by initiating a local inflammatory cascade, which triggers the release of growth factors and collagen deposition. This is accomplished when induced cytokines mediate chemomodulation, which leads to proliferation and strengthening of new connective tissue, joint stability, and a reduction in pain and dysfunction[13]. There is good evidence that prolotherapy is an effective tendinopathy treatment, that significantly reduces neovascularisation which often correlates with clinical improvement[14].

The purpose of this randomized controlled clinical study was to compare the effectiveness and safety of ESWT and dextrose prolotherapy injections in athletes with Achilles tendinopathy and thereby enable faster return to sports.

Objective:-

To determine the effectiveness of ultrasound guided Dextrose prolotherapy injection in comparison with extracorporeal shock wave therapy on improving pain and function among athletes with Achilles tendinopathy

Materials and Methods:-

Study Design:
Randomized Controlled Trial

Study Setting:
Department of Sports Medicine, Regional Institute of Medical Sciences, Imphal, Manipur.

Duration of Study:
1 year starting from July 2022

Study Population:
Patients with pain in the Achilles region not responding to conservative treatment presenting to the out-patient department (OPD) of Sports Medicine, Regional Institute of Medical Sciences, Imphal during the study period

Inclusion Criteria:
1. Clinical and Ultrasound diagnosed cases of Achilles tendinosis
2. Age between 18 to 40 years of age
3. Failure of conservative treatment > 3 months
4. Willingness to comply with treatment and follow up assessment

Exclusion Criteria:
1. Local injection within 6 weeks
2. Local infection at the site of injection
3. Evidence of rupture of Achilles tendon
4. Associated with other diseases
5. Uncontrolled systemic disease
6. Bleeding disorder

Sample size was calculated using the formula $N = (Z_{1-\alpha/2} + Z_{1-\beta})^2 (S_1^2 + S_2^2)/(m_1 - m_2)^2$. Taking into consideration the study conducted by Rompe et al[15] in 2014 a sample size of 26 was calculated and considering a dropout rate of 10%, 29 patients were taken in each group giving a total sample size of 58 patients. Patients who met inclusion and exclusion criteria were recruited based on availability and willingness to take part in the study until sample size was reached. Randomization was done using block of four technique and patients were allocated into two groups namely A=intervention group and B=control group. A list of 15 blocks was prepared to reached a sample size of 58. For each selected blocks, there was sequence of treatment options. The sequence of treatment option in each block was put in an envelope and sealed. Corresponding envelope was labelled 1, 2, 3, 4....upto 15 according to the appearance of treatment allocation in each selected block. The sealed envelope with label 1 was opened only when we had the first eligible patient and the treatment was allocated.

The Study variables were
Independent variables:
1. Age
2. Gender
3. Duration of symptoms
4. Side of affection
5. Interventions
A. USG guided Dextrose Prolotherapy injection
B. Extracorporeal shock wave therapy

Dependent variables:

1. Pain measured by using Visual Analogue Scale (VAS)

The visual analogue scale is a validated scale for subjective measure of pain. It consists of a 10 cm horizontal or vertical line with the endpoints defining extreme limits such as 'no pain at all' and 'pain as bad as it could be'. Patients were asked to mark their pain level that they feel on the line between the two endpoints which represents the perception of their current state. The distance along the line in cm from the 'no pain at all' end of the VAS to the patient's mark represents the numerical index of the severity of pain.

2. Victorian Institute of Sport Assessment - A

The Victorian Institute of Sports Assessment–Achilles (VISA-A) questionnaire is designed specifically for patients suffering from achilles tendinopathy to assess the severity of symptoms, function, and ability to participate in sport. The VISA-A questionnaire contains 8 questions that cover the 3 domains of pain (questions 1-3), function (questions 4-6), and activity (questions 7 and 8). Questions 1 to 7 are scored out of 10, and question 8 carries a maximum of 30. Scores are summed to give a total out of 100. An asymptomatic person would score 100. For question 8, participants must answeronly part A, B, or C.

Intervention:

In the control group a focused electromagnetic shock wave device (EMS Swiss Dolorclast, Munich, Germany) was used. The treatment took place in 3 sessions at weekly interval. In each session, 2400 impulses were administered with a frequency of 8 Hz depending on patient's pain tolerance. According to the principle of clinical focusing, the area of maximal tenderness was treated in a circumferential pattern, starting at the point of maximum pain level. No local anesthesia was applied. Intervention group received a single ultrasound guided dextrose prolotherapy injection. Subjects were positioned in prone position with their feet hanging off the edge of the bed. A 13 MHz transducer with power Doppler imaging was used to examine both Achilles tendons in the longitudinal and transverse planes. The designated injection location was identified before the injection (hypoechogenicity of the tendon). The injection technique involved a single skin portal using a 22G needle and then multiple small aliquots into the tendinous lesion, with color Doppler guidance. Approximately 2 ml of dextrose prolotherapy solution was injected, and no local anesthesia was applied. Needle was removed and local homeostasis will be achieved by applying pressure over the injection site. After the injection, the patient rested in a prone position without moving the leg for 10 minutes, and ice application was done for 10 minutes every 2 hourly. Patients were allowed full loading of the limb after 3 days and could perform normal activities of daily living. If necessary, patients were allowed to use acetaminophen, but the use of non steroidal anti inflammatory medication was prohibited.

Single blinding was done where assessors were blinded. Patients of both Dextrose prolotherapy injection group and ESWT group were given standardized eccentric Achilles tendon strengthening exercises to be followed as described by Alfredson et al[16]. The exercises were performed twice daily in three sets of 15 repetitions with the knee straight and three sets of 15 repetitions with the knee bent for a period of 12 weeks. The participants were told that the exercises may be painful but not to exceed an intensity of 4/10. As the pain eases over time, load was progressively increased by adding weights to a backpack.

Follow Up Assessment:

Outcome variables was measured at baseline before intervention and the participants for both the groups were assessed at the end of 1 week, 4 weeks, 12 weeks and 16 weeks post intervention. VAS was used for assessing decrease in pain; VISA-A score was used to assess the functional improvement. The patients were also be assessed for any intervention related adverse effects.

Statistical Analysis:

Collected data were checked for completeness and consistency. Statistical analysis was done using IBM-Statistical Package for the Social Sciences (IBM-SPSS) Version 21. For descriptive statistics mean, standard deviation and frequency were used. Continuous variables (age, duration of symptoms, VAS, VISA-A) were analysed by student's t-test. Categorical variables (gender, side of affection) were analysed using Chi-square test. Within the group comparison (baseline and follow-up data of each group) was done by repeated measures ANOVA test. Between the group comparison (intervention group and control group) was analysed using student's t-test. A p-value < 0.05 was taken as significant.

Results:-

The 2 groups were homogeneous in terms of baseline characteristics like age, sex, side of affection, VISA-A and VAS scores. No patients were lost to follow-up or had undergone a surgical intervention during the follow-up period. The mean age of the participants was 26.72 ± 5.15 ± in years. The mean duration of symptoms was 6.16 ± 1.22 in months. Males were affected more than females.

VISA-A Score

Within the group comparison showed statistically significant improvement in the VISA-A score from baseline at all follow ups (p=0.00) in both the groups. (Table III). Between the group comparison showed statistically significant improvement in VISA-P scores in both the groups but it was significantly more in the Dextrose prolotherapy group at 12 weeks and 16 weeks (p=0.00) (p=0.03) (Table IV)

Visual Analog Scale (VAS)

Within the group comparison showed statistically significant reduction in the VAS score from baseline at all follow ups (p=0.00) in both the groups. (Table III). Between the groups comparison showed reduction in VAS scores in both the groups but it was significantly more in the Dextrose prolotherapy group at 12 weeks and 16 weeks. (p=0.04 (p=0.03) (Table IV).

Table I:- Comparisons of background and baseline characteristics between the between Prolotherapy group (study) and ESWT group (Control).

Characteristics	Group		p-value
	Intervention Group	Control group	
Mean Age (years)	26.07 ± 5.64	27.38 ± 4.60	**0.337***
Mean duration of symptoms (months)	5.72 ± 1.66	6.27 ± 1.64	**0.210***
Gender			
Male	22	20	**0.770****
Female	7	9	
Side of Affection			
Right	21	17	**0.408****
Left	8	12	

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

Table II:- Comparisons of baseline dependent variables between the between Prolotherapy group (study) and ESWT group (Control).

Characteristics	Group		p-value*
	Intervention Group (Mean ± SD)	Control group (Mean ± SD)	
VAS	6.55 ± 0.98	6.59 ± 1.018	**0.896**
VISA-A	47.66 ± 8.32	51.48 ± 7.35	**0.069**

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

Table III:- Within the group comparison of outcome measures in both groups.

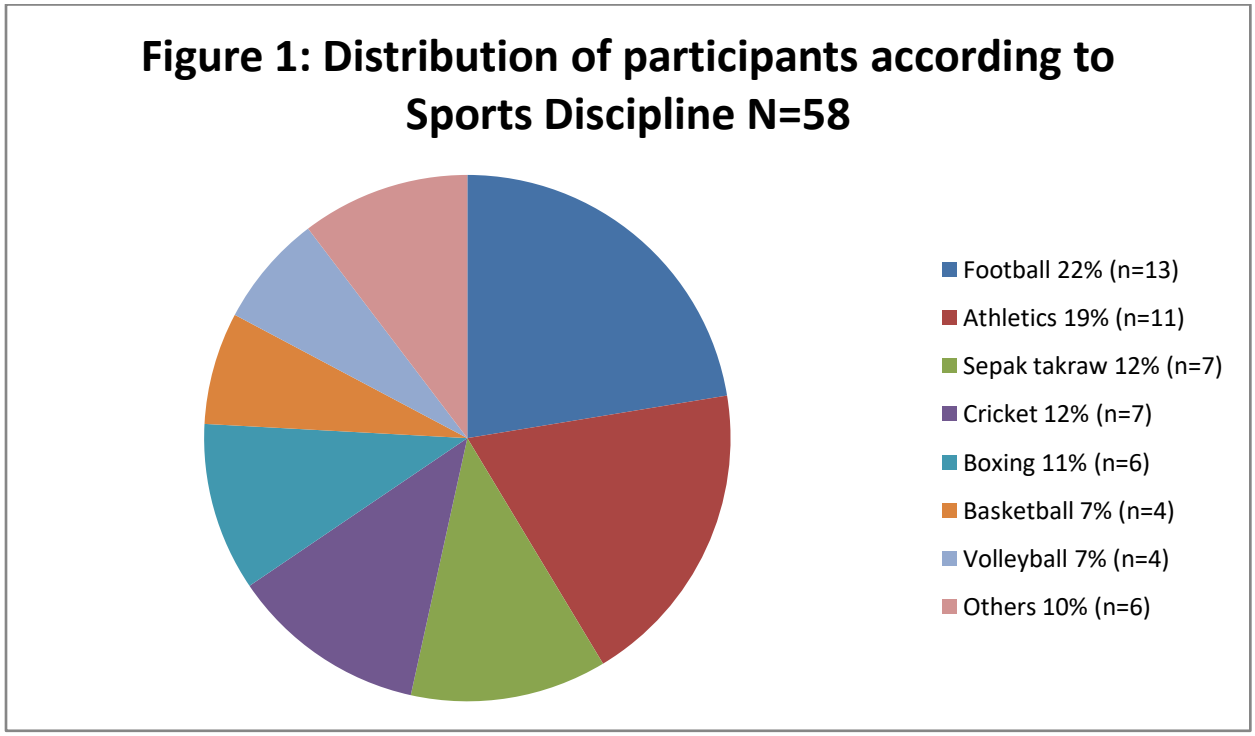
Outcome measures	Study groups	Baseline	4 weeks	12 weeks	16 weeks
VAS	Intervention (Prolotherapy)	6.55 ± 0.985	5.07 ± 0.799	3.24 ± 0.912	1.34 ± 0.857
	p value*		0.00		
	Control (ESWT)	6.59 ± 1.018	3.41 ± 0.780	3.24 ± 0.689	3.07 ± 0.884
	p value*		0.02		
VISA-A	Intervention (Prolotherapy)	47.66 ± 8.32	54.14 ± 7.81	67.14 ± 4.40	84.12 ± 4.50
	p value*		0.00		
	Control (ESWT)	51.48 ± 7.35	61.97 ± 6.76	63.17 ± 8.61	68.42 ± 9.87
	p value*		0.00		

*Repeated measures ANOVA, p-value < 0.05 is taken as significant

Table IV:- Comparisons of mean difference changes from baseline in outcome measures between Prolotherapy group (study) and ESWT group (Control).

Outcome measure	Follow up	Intervention Group (Mean ± SD)	Control group (Mean ± SD)	p- value*
VAS Score	4 weeks	1.48 ± 0.82	3.17 ± 1.33	0.05
	12 weeks	3.81 ± 1.92	3.34 ± 1.31	0.04
	16 weeks	5.20 ± 1.17	3.51 ± 1.15	0.03
VISA-A	4 weeks	-6.48 ± 3.85	-10.48 ± 7.41	0.06
	12 weeks	-19.48 ± 6.66	-11.68 ± 8.14	0.00
	16 weeks	-36.34 ± 9.07	-16.51 ± 10.55	0.03

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



Discussion:-

Achilles tendinosis is a common painful and disabling overuse disorder common especially among sportspersons involving jumping and sprinting activities. Although many different treatment modalities have been described, there is no consensus on the optimal treatment for this condition. This single blinded randomized controlled trial aimed to investigate the possible beneficial effects of ultrasound guided dextrose prolotherapy in comparison with extracorporeal shock wave therapy on improving pain and function in individuals with Achilles tendinopathy. We compared the effects on pain by measuring the VAS while functional assessment was done with the help of the VISA-A score.

Several treatment options have been described in the literature, such as rest, anti-inflammatory drugs, eccentric exercises, injections, and surgical treatments. Extracorporeal shock wave therapy and Prolotherapy injections seem to be a safe and promising part of the rehabilitation program for Achilles tendinopathy. In 2011, Yelland MJ et al[17] conducted a randomized controlled trial to compare the effectiveness of eccentric loading exercises in comparison with single dextrose prolotherapy injection either singly or in combination. The study concluded that for Achilles tendinosis, prolotherapy and particularly ELE combined with prolotherapy give more rapid improvements in symptoms than ELE alone. Ryan et al[18] conducted a study to study the outcome of ultrasound guided dextrose prolotherapy injection for chronic instertional and mid insertional Achilles tendinosis. The study found that Dextrose injections appear to present a low-cost and safe treatment alternative with good long-term evidence for reducing pain from pathology at either the insertion or midportion of the Achilles tendon.

In a review by Gerdesmeyer L et al[12], it was concluded that there is high evidence of efficacy of extracorporeal shock wave therapy in chronic Achilles tendinopathy. Randomized placebo controlled trials have confirmed excellent results with regards to function and pain. However, no differentiation could be done between different treatment modalities such as application pressure, energy flux density or frequency of the waves. In another study by Stania et al[9], it found that Shock wave treatment can be combined with other therapies for better results and suggested that a combination of ESWT and eccentric exercises was an effective treatment for insertional Achilles tendinopathy.

Our study found that both ultrasound guided dextrose prolotherapy injection and extracorporeal shock wave therapy are effective treatment options in the treatment of Achilles tendinosis as both the VAS and VISA-A scores significantly improved at all follow ups. However, it was found that dextrose prolotherapy injections is superior in comparison to ESWT and lead to more significant reduction in VAS pain score and better improvement in VISA-A scores at 4, 12 and 16 weeks follow up.

Time out from competitive play or training due to injury takes a significant toll on the athlete overall. Although both dextrose prolotherapy and ESWT led to significant improvement in outcomes measures, our study found that dextrose injections led to more effective pain reduction and improvement in the function which inturn led to faster rehabilitation and thereby faster return to sports of our athletes. Prolotherapy is a relatively simple procedure that offers a more time-efficient approach to treatment and a better reduction in pain and function at 4 months.

To our knowledge, this is one of the few studies in the country comparing the effectiveness of dextrose prolotherapy in the treatment of Achilles tendinopathy. This study should provide valuable information for future treatment trials of Achilles tendinosis. A combination of both dextrose prolotherapy injection and ESWT in addition to eccentric strengthening exercises could possibly be a more effective treatment option and further trials are required. A longer follow up and a larger sample size would have been ideal however due to time constraints and other unforeseen circumstances it was not feasible.

Conclusion:-

Although both dextrose prolotherapy injections and ESWT are safe and effective in the treatment of athletes with achilles tendinopathy, dextrose prolotherapy injection under ultrasound guidance in addition with eccentric loading exercises of Achilles tendon was significantly more effective on improving pain and function than ESWT at 4 months.

Ethical Clearance:

Ethical approval of the Research Ethics Board, RIMS, Imphal was taken for this clinical study.

Financial Support & Sponsorship:
No financial support or sponsorship.

Limitations:

Although the assessment was blinded, there was no way to blind the patients to the treatment. Therefore, it is possible that their awareness of the treatment modality may have had some effect on their perception of their response to the treatment. The follow up period perhaps could have been for a longer period of time which was not possible in our study due to certain difficulties.

Conflicts Of Interest:
None.

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