"CLINICAL EVALUATION OF FUNCTIONAL OUTCOME IN LATERAL EPICONDYLITIS BY LOCAL INJECTION OF AUTOLOGOUS BLOOD".

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This is to certify that the dissertation entitled **"CLINICAL EVALUATION OF FUNCTIONAL OUTCOME IN LATERAL EPICONDYLITIS BY LOCAL INJECTION OF AUTOLOGOUS BLOOD"** is a bonafide research work done Reg no. BL0119002

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List Of Abbrevations:

TE: Tennis Elbow
LE: Lateral Epicondylitis
ABI: Autologous blood injection.
ECRB: Extensor Carpii Radialis Brevis
NPS: Nirschl Phase Scoring
VAS: Visual Analogue Score
PRP: Platelet Rich Plasma
DASH: Disabilities of the Arm, Shoulder, Hand
OCD: Osteochondritis Dessicans
RCT: Randomised Control Traiol
NSAID : Non Steroidal Antiinflammatory Drugs
N: Non Dominant
D: Dominant

Abstract :

Background: Tennis elbow (TE) is a common myotendinosis. It was first described by Runge in 1873; different modes of treatment are used in management of TE. It has a yearly incidence of 4-7 instances per 1000 people, with peak ages of 35-54 years and a mean age of 42 years .

Objectives: This study aimed to report the results of autologous blood injection (ABI) in the treatment of TE.

Materials and methods: A prospective case study was performed to evaluate the results of ABI in the management of TE. The level of pain based on Nirschl phase scale (NPS) and a visual analogue scale (VAS) was calculated before and 2 weeks, 6 weeks, 12 weeks, 24 weeks after injection; then satisfaction was assessed.

Results: Forty patients with diagnosed TE were treated by ABI (52.5 % males, 47.5 % females). The mean age of the male patients was 44.5 ± 6.2 years and mean age of the female patients was 41.3 ± 5.2. The level of pain on VAS decreased from 8.375 ± 1.03 to 2.875 ± 1.869 (P=0.0001) and on NPS from 6.275 ± 0.134 to 2.250 ± 0.237 (P = 0.0001) 6 months after treatment. At the end of the study, 90% of patients expressed a high level of satisfaction.

Conclusions: Given the acceptable outcomes, autologous blood injection can be considered a good treatment option for TE when traditional treatment has fails.

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INTRODUCTION

Tennis elbow (TE) is a prevalent problem in orthopedic practice. It is the second most often diagnosed disorder of musculoskeletal in the neck and upper extremities in a primary health care setting[1]. Tennis elbow is a kind of myotendinosis that was initially identified in 1873 by Runge. It has a yearly incidence of 4-7 instances per 1000 people, with peak ages of 35-54 years and a mean age of 42 years[2,3,4,5].

Pain and tenderness above the lateral epicondyle are the most common clinical signs[1]. Repeated usage from a variety of activities has been associated to lateral epicondylitis[1]. Rather than being an inflammatory condition, it is characterized by angiofibroblastic hyperplasia and degeneration inside the common tendon of the extensor, mostly affecting the extensor carpi radialis brevis[12]. Inflammation is not the predominant etiological event in lateral epicondylitis, according to histology[5,6,7]. Repetitive micro trauma and inadequate healing contribute to tendon deterioration. As a result, the illness is known as tendinosis, which is a degenerative disorder[8,9,10,11,12,13].

The pain above the root of the extensor carpi radialis brevis muscle is used to diagnose tennis elbow. 5mm distal and anterior to the midpoint of the lateral epicondyle, tenderness can be felt. Resisted wrist dorsiflexion and forearm supination, as well as discomfort when holding things, generally worsen the pain. X-rays are usually unremarkable; however calcified tendinitis can occasionally be seen. On MRI, higher T1 and T2 signals show that the tendons are thickening.

Conservative treatments include activity modification, rest, bracing, physical therapy, NSAIDs, local injections, phonophoresis, iontophoresis, laser therapy, extracorporeal shock wave therapy, botulinum toxin, acupuncture[4], and surgical treatments such as extensor origin release, debridement and de-nervation of the lateral epicondyle, and anconeus rotation[15].

NSAIDs and local corticosteroid injections are two of the most widely utilized therapy approaches, both of which have minimal intermediate or long-term benefits[16]. This might be related to the absence of inflammation in the disease's etiology.

In the management of lateral epicondylitis, an autologous blood injection (ABI) was recently reported to be effective for both intermediary and long-term results, with a significant reduction in pain[1,8,13,17]. Local autologous blood infusion (ABI) provides necessary chemical regulators of cellular activity known as mitomorphogenic[7,18,19,20], which aids healing. Local ABI provides the cellular and humoral mediators necessary to start the healing process.

It's a prospective clinical trial with the goal of determining the functional result of local autologous blood injection for lateral epicondylitis. ABI was chosen as it is easy to get, inexpensive, less traumatic, has a low risk of immune-mediated rejection.

OBJECTIVES

The purpose of this study was to evaluate the functional result of patients who had received autologous blood injections.

REVIEW OF LITERATURE

The earliest clinical description of lateral epicondylitis was published in 1873, and it was connected to prolonged arm usage while writing[21]. Later, workers in a range of industries, such as carpenters, plumbers, and violinists, acquired lateral epicondylitis symptoms.

Tennis elbow was first identified in 1982 as a pronator radius sprain caused by an aggressive backstroke that causes rapid and extensive pronation of the forearm[22].

It was initially identified in 1936 as a condition with symptoms and signs comparable to lateral epicondylitis. The exact cause of lateral epicondylitis is unknown. Despite the fact that there are 26 different pathological explanations documented, the facts is overwhelming in favor of an unique TE caused mostly by

damage between the tendinous origin of the ECRB and the lateral epicondyle periosteum[23]. It was supported up by a study done in 1979[24].

According to a 1973 study, lateral epicondylitis was induced by force overload (The elbow has a mechanical predisposition to force overload due to an inadequate lever system.). 1) Intrinsic overload occurs when forearm extensor strength and stamina are insufficient to sustain the force transmitted to the forearm. 2) Extrinsic overload caused by a lack of forearm extensor suppleness, 3) Extrinsic and intrinsic overload caused by prolonged periods of force or duplication in a person with adequate muscle flexibility, strength, and endurance[25].

A study published in 1979 discovered that 88 surgical elbows were linked to lateral epicondylitis in tennis and golf players (in the non-dominant arm), but it might also affect non-tennis players[26].

In 1990, "overuse" was described as the degree of rhythmic micro trauma that was sufficient to overwhelm the tissues ability to acclimate, resulting in injury[27].

The ultimate cause of lateral epicondylitis, according to a study published in 1993, is a combination of the time interval and overall strength of limb usage. The most commonly implicated structure for lateral epicondylitis is common extensor origin pathology, notably the ECRB[28].

The extensor origin was determined to be grossly normal in 57 out of 63 surgical elbow cases studied in 1993. In 46 percent of the instances, there was vascular growth, 27 percent had mucin-like material breakdown, and the other 27 percent had no indication of an inflammatory influence. Unstructured white steroid compound was identified in five people[29].

According to a study published in 2002, “Lateral epicondylitis is a common condition that has been extensively studied but is still poorly understood. It's not simple to pinpoint the exact location of the pathology that's causing the

discomfort". Changes in the extensor digitorum muscle induced tennis elbow, which was validated by a positive Maudsley's test[30].

A study was done in GSVM medical college, Kanpur, India in 2009 by Dr.Ajay Bharti et al. who included 25 patients in this study. They were infiltrated with local autologous blood with local anesthetics and assessed using VAS scoring and Verhar et al. scoring system. The patients were followed for 12 weeks and 64% of show excellent and 32% show good results and one patient had poor outcome. Thus this study concludes ABI is a safe and useful modality in the management of TE[31].

Mahmood Karimi et. al conducted a study with the goal of reporting the outcomes of ABI in the management of tennis elbow. Retrospective study was done on 29 patients who evaluated the results of ABI in managing the lateral epicondylitis. Evaluated using Visual analogue scale (VAS) and Nirschl Phase Scale (NPS). When usual treatment fails, autologous blood injection might be regarded a promising therapeutic option for tennis elbow, according to the study[32].

A study was done in 2014 by Dr.Naseem ul Gani et al. In a prospective study done between 2005 to 2011, 125 patients were included who did not respond to conventional treatment including local corticosteroid injection , was treated with autologous blood injection and were followed for 3 years. Patients were assessed using a pain rating scale and Nirschl score. The mean pain score and Nirschl score before the procedure and after the procedure have reduced. As a result, autologous blood is a low-cost, readily available, and simple therapy option that should be evaluated before undergoing surgery[33].

A study was done in 2016 by M.A.Q.Ansari et al. randomised prospective study of 48 people was grouped consecutively into two groups of 24 each. Group I patients was given autologous blood injection and Group II patients were given injection normal saline. Results showed that incidence is more in the third decade 39.6%

with female preponderance 58.3% and dominant arm commonly involved 58.3%. Excellent results were found in group I (Autologous blood injection group) 62.5% when compared to group II (injection normal saline) 58.3%. As a consequence, autologous blood injection is a very effective minimally invasive surgery that yields satisfactory results in individuals who have failed to react to previous conservative therapy approaches[34].

In 2012, Nicola Massy Westropp et al. published a research on patients with lateral epicondylitis who were treated with autologous blood injection (under ultrasound guidance) after cortisone injections failed. A prospective longitudinal research comprising 40 patients, 38 of whom completed the trial and were assessed using patient-rated tennis elbow scores. Patients were evaluated before and after injection at 6 months, 18 months, and 5 years, and pain was reduced to 2 to 5 on the visual analogue pain scale, and self-perceived function improved by 11 to 25 out of 100. Grip strength was much higher in women than in males. According to the findings, autologous blood injections improved pain and function in a worker's compensation cohort of people with chronic lateral epicondylitis who had not gotten relief from corticosteroid injections[35].

When Edwards and Calandruccio et al. studied autologous blood injections in 28 patients with lateral epicondylitis who had failed to respond to conservative therapy, they observed that 22 patients (79 percent) reported reduced pain after 9.5 months. Most of the patients have maintained their maximal benefit during their follow-up examination, with no recurrence[36].

Mangal Rawal et al. conducted a research in 60 consecutive patients with untreated lateral epicondylitis in a prospective randomized trial in 2017. The two groups were randomly assigned on an alternating basis, with the one getting corticosteroid injection and the second receiving autologous blood injection. A VAS score and Nirschl's score were used to evaluate both groups. The functional score in

autologous blood (excellent-73%) is higher than in the steroid group (excellent-36.6%). Short-term outcomes of autologous blood injection are superior to corticosteroid injection in patients with tennis elbow, whereas long-term results are equivalent to steroid injection in terms of VAS score, Nirschl's stage, and functional score[37].

A randomized control trial with 60 participants was conducted to compare the effectiveness of autologous blood injection vs. local corticosteroid injections. When comparing the cortisone group with the autologous blood injection group, the results indicated that the cortisone group had much less pain, while the autologous blood injection group had significantly less adverse effects. The author found that autologous blood injection is more successful than corticosteroid injection, with fewer adverse effects and a decreased chance of recurrence, when compared to corticosteroid injection[38].

The clinical results of platelet-rich plasma, autologous blood, and corticosteroid injection were compared in a systematic review and network meta-analytical analysis. From January 2015, the Medline and Scopus databases were searched using weight regression for dichotomous outcomes. When comparing platelet-rich plasma to autologous blood and steroid injections, the study found that autologous blood, corticosteroid injections improved DASH score. Autologous blood injection can reduce pain, disability score, and pressure pain threshold better than PRP, but it comes with a higher risk of consequences, according to this study[39].

Relevant Anatomy[40]:

Elbow forms at distal end of humerus and the proximal end of the radius and the ulna as a hinge joint articulation. Stability of elbow depends on the bone congruity and capsuloligamentous envelope. The shaft of humerus is triangular in the axial section at its middle, flattens anterioposteriorly and broadened transversely

distally. Medial and lateral condyles are cancellous bones forms at the distal end of humerus. The lateral condyle is surmounted by the capitellum, a dome shaped prominence that articulates the shallow concavity with the radial head. Superior to the capitellum on the anterior surface of the humerus is a shallow fossa that accommodates the head of the radius on full extension of the elbow.

The trochlea is a spool shaped process surmounting the medial condyle that articulates with a notch in the upper extremity of the ulna. The medial rim of the trochlea is prominent, extending a little distally. Trochlea is completely covered with articular cartilage till the olecrenon fossa. Proximal to the trochlea the humerus is thinned out to form the coronoid fossa and the olecrenon fossa. These accommodate the coronoid process of the ulna in flexion and the tip of the olecrenon process in extension.

Just above the medial and lateral condyles there are bony prominences for the tendious attachment called epicondyles. The tendious attachment of the flexor pronator group of muscle originates from the medial epicondyle. Similarly, the tendinous attachment of the extensor supinator group of muscle originates from the lateral epicondlye. Both the condyles lie outside the synovial cavity of the elbow. The collateral ligament attaches to the respective epicondyle on each side of the joint.

The expanded upper extremity of ulna is formed anteriorly by the coronoid process and posteriorly by the olecrenon process. Between the two is the deep is a semilunar notch, the greater sigmoid fossa which articulates with the trochlea. Incisura radialis or lesser sigmoid notch is situated on the lateral side of the ulna and distal to greater sigmoid notch.

Radius has a disc shaped head which is enclosed with the cartilage and lies within the synovial cavity and proximal surface is concave which articulates with the capitellum.

Capsular ligaments and synovium :

The elbow is covered in a fibrous capsule which attaches proximally to the humerus just above the olecrenon and coronoid fossae, distally to the ulna just above the sigmoid notch. The capsule

is thin, pliable, redundant anteriorly and posteriorly to permit free flexion and extension. Collateral ligaments on the inner and outer aspects of the capsule, are tense and provide stability by preventing mediolateral motion.

The medial (internal) collateral ligament is a ligament that runs from the medial epicondyle to the larger sigmoid fosse's edge. The lateral (outer) collateral ligament runs from the lateral epicondyle to the annular ligament, where it merges.

Orbicular (annular) ligament encircle the radial head and joins distally to the radial neck and medially to the anterior and posterior edges of the smaller sigmoid fossa of the ulna.

Synovial membrane lines, inner surface of the capsule. Synovial sacs are formed proximally where the membrane is reflected onto the humerus above the olecranon and the coronoid fossae and extends to the articular margin. Distally, the membrane forms a recess where it is reflected at the neck of the radius. In latter situation, the radial head and a portion of the neck lie entirely intrasynovial, explaining the ease with which fracture fragments of the radial head are displaced.

Bursae:

Two bursae lie in relation to the triceps tendon insertion. One lies between the triceps tendon and the upper surface of the olecranon. The other, lies between the skin and the dorsal surface of the olecranon.

Elbow Motion:

Elbow is a hinge joint, flexion and extension occurs between the distal end of the humerus and the proximal ends of the radius and ulna. The full extension with the forearm lying in the axis of the arm is designated as 180 degrees. The degree of flexion is measured by the angle which the forearm forms with the arm as it approaches the latter, the normal being 130 degrees. The 30^0 to 130^0 arc is required to perform all activities in life.

Rotatory motion (supination or pronation) occurs at the proximal radiounlar joint and the distal radioulnar joint. At the elbow, the edge of the disc shaped radial heads glides in the lesser sigmoid notch and pivots about the prominence of the capetillum. During the pronation, the distal end of radius swings dorsally and

comes to lie medial to the head of the ulna. Disruption of either distal or proximal radioulnar joint or a disturbed capetillum radial head relationship will limit the rotatory motion.

Muscles :

Posterior: Triceps attaches through the aponeurosis to the olecranon and helps in extension of the elbow.

Anterior: Biceps which inserts into the bicipital tuberosity of the radius and helps in flexion and supination. Brachialis which inserts in the coronoid process of the ulna helps in flexion.

Medial to biceps and brachialis, the flexor pronator group of forearm muscles takes origin by the conjoined tendon from the medial epicondyle of the humerus. These muscles helps in flexion of the elbow.

Lateral to the biceps and brachialis lies the coracobrachialis, originates through the lateral supracondylar ridge of the humerus, and lateral to this is the extensor group of muscles of the wrist and hand is seen.

Pathophysiology-

Trauma caused the majority of acute tendon damage. Tendinosis occurs when internal structures of the tendon are disrupted as a result of a micro-traumatic condition in the tendon. This injury is most commonly noticed in those who have been overusing their bodies for an extended period of time.

Tendons that are involved in ballistic performance and locomotion, as well as those that transmit stresses under eccentric circumstances and are elastic, are susceptible to damage. Tendons that travel through two joints, have a limited vascular supply, or are used repeatedly are at risk of chronic overuse damage[41,42,43,44,45].

Small injuries that occur often cause tendon deterioration. Micro-traumatic events occur several times, resulting in chronic overuse injuries. Tendon internal structure is disrupted, and cells and matrix degradation occurs, resulting in tendinosis.

The early lesion is due to hypoxia degradation rather than inflammatory processes, which might be a natural aspect of ageing or a reaction to stress from overwork or misuse[46]. It's also been suggested that in areas with low vascularity, a partial healing cascade characterized by fibrous and vascular growth occurs.

Tendon intra-substance proliferates, resulting in degeneration in the inadequately vascularised region, with histology revealing cellular atrophy, reduced protein synthesis, and cyst development[47]. The tendon weakens and ultimately micro ruptures as the deteriorated region grows larger, triggering the usual inflammatory response and healing cascade.

Tendinosis is a condition that is not totally understood. Despite the common use of the term tendinitis, histological results from the overuse tendon site show no macrophages, neutrophils, or lymphocytes in significant numbers[9,10,11].

Tendinosis has been described as a degenerative process in a few papers, and even fewer as an immature tendon repair in still fewer[9,11,48,49,50,51,52,53]. Angiofibroblastic hyperplasia is the name given to this condition. Though it is named such, it is caused by a failure of the tendon to repair after repeated micro trauma.

Origin of the extensor carpi radialis brevis is the most common location of injury in lateral epicondylitis, it is reliably linked to pathological alterations[54,55,56]. Histological investigations show that a vascular response and fibroblastic alterations cause lateral epicondylitis, which leads to angiofibroblastic degeneration, commonly known as tendinosis[57]. As a result, the terms tendinitis and epicondylitis are misnomers. Although it is usually assumed that nociception and a noxious chemical environment cause every inflamed painful structure to be recognized by the patient, connective-tissue pain can also be recognized as a result of nociception and a noxious chemical environment. Adolescent scar tissue is typically black, sticky, friable, edematous, and glossy in that region.

Microscopy-

Collagen is positioned in the long axis of the tendon in normal tendon microscopy, and collagen bundles are parallel to each other and homogeneous. Glycosaminoglycans, water, and proteoglycans make up the majority of the matrix. The tendon has a visible vascular structure. In one investigation, an invasion of round cells, fibroblasts, and vascular tufts was shown to be pathognomonic of epicondylitis[56].

Tendinosis is defined as a disruption in the ordered arrangement of tendon fibers accompanied by fibroblast invasion and unusual granulation tissue[54,57]. It's also known as localized hyaline degeneration with a still-developing reparative mechanism[46].

Electron Microscopy:

Fibroblasts show open nuclear chromatin, significant levels of collagen synthesis at the cell's periphery, fibroblasts, and contractile components under electron microscopy. There are two sorts of fibroblasts in this state: those that lack contractile components and those that do. Fatty vacuolation and lysosomes were seen in both types of fibroblasts, as well as a lot of endoplasmic reticulum[58,59].

Clinical Presentation:

The patient suffers from lateral elbow and forearm pain that becomes worse with activity. A 30-55-year-old woman or man who engages in rigorous daily activities and is a recreational athlete is more likely to experience symptoms. Tennis elbow patients commonly experience discomfort above the lateral epicondyle.

The pain usually radiates into the dorsal forearm, however it can also radiate proxi mally. It grows as a result of grabbing and lifting. The patient recalls a history of pain that has been triggered by everyday chores such as lifting pots and pans or clutching a water container. The location and consistency of pain are the most crucial diagnostic findings[60,61]. The patient's ECRB muscle exhibits a maximum

point of discomfort just distal to 5mm to 10mm of the lateral epicondyle, according to examination.

A variety of clinical tests have been recommended, the most popular of which being Cozen test and Mill's maneuver.

Chair raise test- When patients with tennis elbow stand behind a chair and try to lift it by putting their hand on the back of the chair, they experience discomfort in the lateral elbow region.

Cozen’s test- Complains of pain in the lateral elbow region when asked to passively bend the wrist while forming a strong fist.

Mill’s maneuver- Because this will produce discomfort in the lateral epicondylar region, ask the patient to extend the elbow and wrist flexed in a pronated forearm.

Chair test- Ask the patient to get out of the chair while holding both hands on the chair's arms, which will cause discomfort in the lateral epicondylar area.

Diagnosis

Clinical tests are used to make a diagnosis, and further testing is normally done simply to rule out alternative disorders. Radiographs to rule out intra-articular disease such as osteophyte and osteochondral loose body, as well as calcification in the ECRB muscle origin, as needed.

The use of magnetic resonance imaging (MRI) can aid in the detection of degenerative disease in the ECRB muscle. It has a smooth, well-defined, homogenous structure on MRI sequences. On a T1 weighted picture, a low to intermediate signal shift can be noticed early on. With fat suppression cystic alterations seen in late stages, T2 weighted sequences indicate a rise in signal. Ultrasonography (USG) reveals calcification, thickness, surrounding bone irregularity, localized hypo echoic patches in the tendon, and wide spread tendon heterogeneity in the common extensor tendon.

Other Tests:

Electromyography (EMG) can be used to rule out posterior interosseous nerve compression syndrome when clinical examination suspects neural disease. There will be pain alleviation after a local anesthetic injection near the ECRB muscle's origin, which will aid in establishing the diagnosis.

Differential Diagnosis:

Other disorders that might cause discomfort in this area, such as cervical radiculopathy, radial tunnel syndrome, OCD of the capitellum, lateral compartment arthrosis, and varus instability, be included in the differential diagnosis of this illness.

Treatment:

Surgical and non-surgical treatments are available for lateral epicondylitis. The various therapy options work by reducing inflammation, changing biomechanics, and repairing tendonopathy[62]. In 95 percent of cases, non-operative therapy is effective[63]. The majority of lateral epicondylitis patients are treated conservatively[64,65].

Avoiding work, rest, applying local cold, administering local injections, and employing ultrasonic physical therapy, electrical stimulation, manipulation, soft tissue mobilization, stretching, bracing counterforce, and friction massage are among non-operative treatments.

ESWL [extracorporeal shock wave lithotripsy] has had favorable outcomes in the past, but subsequent trials have had mixed results. In one study, there was no difference between forearm stretching alone and forearm stretching plus ESWL. ESWL was shown to be ineffective in lowering pain and increasing function in a double-blind, randomized, placebo-controlled experiment[63].

One to two steroid injections at the site of highest soreness have been found to be beneficial in some individuals. Autologous whole blood injection produced positive effects in certain patients. PRP (platelet rich plasma) local injections have

been shown to improve function and relieve pain better than local corticosteroid injections. According to a recent systematic study, both PRP injection and autologous blood injection can reduce pain, however autologous whole blood injection has a greater risk of complications.

For chronic tennis elbow, a direct comparison of PRP injections (28 patients) and surgery (50 patients) yielded similar benefits. Two ultrasound guided PRP injections were found to be no more effective than saline injections in a controlled randomized clinical study. Based on the available evidence, no strong conclusions can be drawn concerning the efficacy of PRP or autologous whole blood injections, or if one procedure is preferable to the other[63].

Only after conservative treatments have failed for 6-12 months, surgery is considered[63].

Intraarticular- Boyd,.McLeod, and Almquist procedures (anconeus interposition),

Extraarticular- Debridement, excision, lengthening of ECRB, and reattachment[66],

Open fasciotomy and release of extensor aponeurosis,

Percutaneous lateral release of extensor origin,

Lateral epicondylectomy,

Arthroscopic release are all common techniques.

A thorough investigation of the efficiency of several therapy for lateral epicondylitis was undertaken in 1992. Five (randomized) clinical assessments of steroid injections published in English between 1966 and 1990 were included in the research. They came to the conclusion that there is inadequate scientific data for any specific therapy for tennis elbow due to low standard of practice and inconsistent outcomes[67].

In 1996, a rigorous review of the efficacy and outcomes of an RCT of corticosteroid injections for tennis elbow was conducted. The outcome of therapy was evaluated using a pain score. Pooled analysis was only useful for determining

short-term outcomes (2to6 weeks). There was no difference between alternative treatments and corticosteroid injections after a 6-week follow-up. There were no results reached about the optimum corticosteroid, injection volume, dose, or injection interval[68].

In 1999, 164 people with new-onset tennis elbow participated in a randomized controlled trial (RCT) that evaluated oral non-steroidal anti-inflammatory (NSAID), analgesics, and corticosteroid injection. Patients in the corticosteroid group were "improved" at four weeks, compared to 48 percent in the NSAIDS group and 50 percent in the other pain treatment group. After a year of investigation, however, all of the groups reached the same results[69].

In a 2002 research, corticosteroid injection resulted in statistically significant and clinically important changes in overall improvement, pain, and grip strength for local anesthesia and conservative therapy for short-term outcomes (>6 weeks) when compared to placebo. There were no discernible impacts after a long and intermediate period of observation. More and better studies are needed, as well as RCTs with long-term and intermediate-term follow-up that have been completed and published[70].

Corticosteroid injections were found to have beneficial effects after six weeks in a 2006 study. When compared to physiotherapy or a wait-and-watch method, long-term results were poor, thus they were not statistically different[71].

Intra tendinous corticosteroid injection has been proven in animal experiments to have deleterious effects on the mobility and structural characteristics of tendons. Corticosteroid injection prevents adhesions and granulation, decreasing the bulk of the tendon and hence the amount of stress and biomechanical integrity[72,73]. Rupture of a human tendon as a result of a corticosteroid injection around the tendon is a common event recorded in various case reports[74,75].

The injection of corticosteroids produces a multitude of adverse effects. One out of every 17 soft tissue or intra-articular steroid injections is connected to sepsis[76]. Another side effect is pain secondary to injection (11-58 percent). In 17 to 40% of instances, local skin shrinkage or atrophy, facial flushing, flare post injection site, hyperglycemia, and hypersensitivity reactions occur[75,77]. Resuscitation equipment should be ready if a patient has a severe reaction[77].

Young patients, systemic or local infection, tendon injury, and coagulopathies are all contraindications for corticosteroid injection[77,78].

A study on 28 patients who were treated with conservative therapy was undertaken in 2003. After 9.5 months, 79 percent (22 of 28) of tennis elbow patients experienced decrease in pain severity following autologous blood infiltration. This happened more often after a single dose. The activation of transforming growth factors, fibroblastic mitosis, and chemo attractant polypeptides is one of the theories. Angiogenesis is induced by mitogens such as platelet-derived growth factor. As a result, a particular humoral mediator stimulates the healing sequence in tendinosis[79,80].

Another research found that local infusion of platelet rich plasma into tennis elbow patients resulted with a significant decrease in discomfort. A total of 144 individuals with elbow discomfort owing to tennis elbow were assessed. For pain alleviation, 20 individuals had surgery. Following that, these patients had a single percutaneous injection of PRP or bupivacaine (control group). The authors saw a 60 percent improvement in pain after 8 weeks of treatment, while the control group only had a 16 percent improvement. The group that got platelet-rich plasma continued to report considerable pain reduction at six months and at the latest follow-up (mean 25.6 months)[81].

Sonography-guided blood injection improves clinical results, and it proved beneficial for assessing alterations in the common origin of extensor[82].

Autologous blood injections have recently been shown to be effective in the treatment of lateral epicondylitis in both the short and long term, with a significant reduction in pain. Local autologous blood infiltration can provide mitomorphogenic chemical modifiers of cellular activity, which assist healing. Local autologous blood infiltration is thought to provide the cellular and humoral mediators needed to start the healing process[31].

METHODOLOGY:

Source of data:

Patients with 30 to 55 years of age and of any gender present with typical features of lateral epicondylitis of either elbow after being clinically diagnosed as suffering from lateral

epicondylitis/tennis elbow at the outpatient department of KLE Prabhakar Kore's Hospital Belagavi.

Study design:

A hospital-based observational study

Study Period: The study will be conducted from Jan 2020 to Dec 2020.

Sample size :

The minimum sample size formula based on the rate of percentage is n = where P is the percentage of recovery and d is the percentage expected difference in P.

The significance level is related to $z\alpha$. For 5% level of the significance $z\alpha = 1.96$.

Ref: Partap Singh et al., a study done for the treatment of lateral epicondylitis, a comparison of local steroid injection with autologous blood.injection therapy was conducted, 88% of patients treated with autologous blood are having total pain relief.

With P = 88% and d = 10% of P = 8.8%, the sample size is 52.

Taking into consideration the likely loss in the follow-up, the sample size will be increased to 60.

Sample size is reduced to '40' cause loss of patient intake due to COVID 19 pandemic and resultant lockdown.

Study requirements:

Patients with lateral epicondylitis willing to undergo explained procedure of autologous blood injection.

Selection criteria:

Inclusion criteria:

Patients clinically diagnosed with lateral epicondylitis of either gender.

Patients with 30-55 years of age

Exclusion criteria:

Patients suffering from other causes of elbow pain such as RA, OCD, gouty arthritis, radial tunnel syndrome, cervical lesions, and shoulder pathology.

Previously managed with corticosteroid injections.

Previously underwent surgery.

At the injection site, there is localized skin pathology.

Methods:

Procedure:

The Institutional Ethical Committee Review Board granted ethical approval.

The study's goal will be explained, and all participants will provide written informed permission.

Inclusion criteria, exclusion criteria will be used to choose the subjects.

Over the course of a year, the study will be done.

After the patient signs the informed Consent form, the history and examination should be documented according to the proforma. Patients with characteristic symptoms of pain and discomfort over the lateral epicondyle and clinically diagnosed to have tennis elbow. A detailed history and clinical evaluation, including Cozen test and Mill's maneuver, was performed .

Local autologous blood injections were given to the patients. The findings were recorded using a visual analogue scale (VAS) and nirschl scoring. The scores will be recorded in the given proforma on the day of injection, before the injection is delivered, and again after 2 weeks, 6 weeks, 12 weeks, and 24 weeks. The data will be evaluated using non parametric tests such as the Kruskal–Wallis test and the Mann–Whitney U test. For immediate pain relief, patients will be given paracetamol following the injection. After the injection, patients are encouraged to rest for the first two weeks by refraining from intense activity with the affected extremity.

2 milliliters of venous blood is drawn through the contra-lateral upper limb of cubital vien.

The origin of the forearm extensor tendons, particularly the ECRB tendon, which is 5 mm from the lateral epicondyle, is the injection site. The skin will be painted using povidone-iodine and ethyl alcohol. Instead of being injected within the tendon, two milliliters of autologous blood will be injected on and around it. If the injection encounters any resistance, the needle is retracted a bit and the injection is repeated. Patients will be given instructions on how to care for themselves after receiving an injection. The patient will be informed if the discomfort increases within the first two weeks. Pain relief is provided by paracetamol. Two-week, six-week, three-month, and six-month follow-ups are required.

Procedure to be done under aseptic precautions with antibiotics are given as a precautionary measure.

The VAS score and Nirschl grading of lateral epicondylitis were used to assess the outcome.

Pain score:

Visual analogue score:

It consists of a 10-centimeter line marked with no pain on one end and the severe agony on the other. The participant is invited to place their pain on the line. Where the patient marks on the scale, a numerical value is presented.

Painless 1—2 –3—4—5—6—7—8 –9—10 Awful pain ever

Nirschl scoring:

Phases of pain:

Benign Pain

Phase 0: Lack of pain

Phase 1: Stiffness or mild soreness after exercise activity. Pain is usually gone in 24 hours.

Phase 2: Mild discomfort and soreness prior to exercise that subsides as you warm up. There is no discomfort during exercise, but there is slight soreness afterward that goes away within 24 hours.

Phase 3: As before, but with moderate discomfort during exercise that does not interfere with activity and goes away in 24-48 hours. In this case, counterforce bracing and mild anti-inflammatory medicine may be considered.

Phase 4: Mild to moderate pain before, during, and after exercise that causes the exercise or behavior to change. ADLs are harmed. Phase 4 indicates that tendon damage has occurred.

Phase 5: Moderate to severe pain prior to, during, and after exercise or operation, requiring the patient to stop exercising. Pain is felt while doing ADLs. Usually indicates long-term tendon injury.

Phase 6: Pain from Phase 5 that continues despite full rest. ADLs are disrupted by pain, and several behaviors must be eliminated.

Phase 7: Consistently disrupted sleep as a result of phase 6 discomfort. Pain is aching in nature and gets worse when you get more involved.

Statistical analysis :

Since the study is of observational study the plan of analysis will be as follows.

The mean and standard deviation will be calculated for continuous quantitative data. If the data is separated into two groups based on a qualitative trait, the continuous variables will be compared using appropriate statistical methods such as the student's unpaired t test for comparison. The student's paired t test will be used to compare before and after therapy measurements or measures collected at different time intervals.

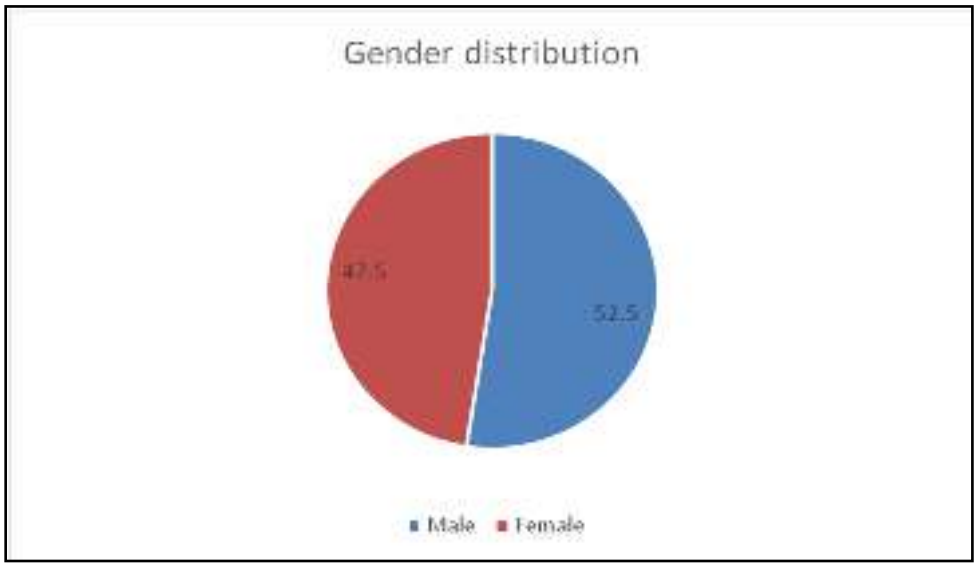
Discrete variables will be represented by median.

Rates, ratios, and percentages will be used to express categorical data. The Chi-square test, test of proportions, or Fisher's exact test will be used to examine the relationship between the outcome, clinical, and demographic characteristics. For discrete variables nonparametric tests will be used.

Suitable graphs will be used to depict the comparison.

All tests will be considered significant if the p value is less than 5% (0.05).

RESULTS:



Distribution of subjects based on gender

Figure no.1

Figure 1 shows 52.5 % are males and 47.5 % are females

Gender vs side

	Side		
	Right	Left	Total

Sex	Male	Frequency	17	4	21
		Percentage	81.0%	19.0%	100.0%
	Female	Frequency	12	7	19
		Percentage	63.2%	36.8%	100.0%
Total		Frequency	29	11	40
		Percentage	72.5%	27.5%	100.0%

Table no.1

Table 1 explains about right sided males are 81% and 19% left sided males; right sided females 63.2% and left sided females are 36.8%.Total percentage of right sided are 72.5% and left sided are 27.5%.

Distribution of subjects based on side

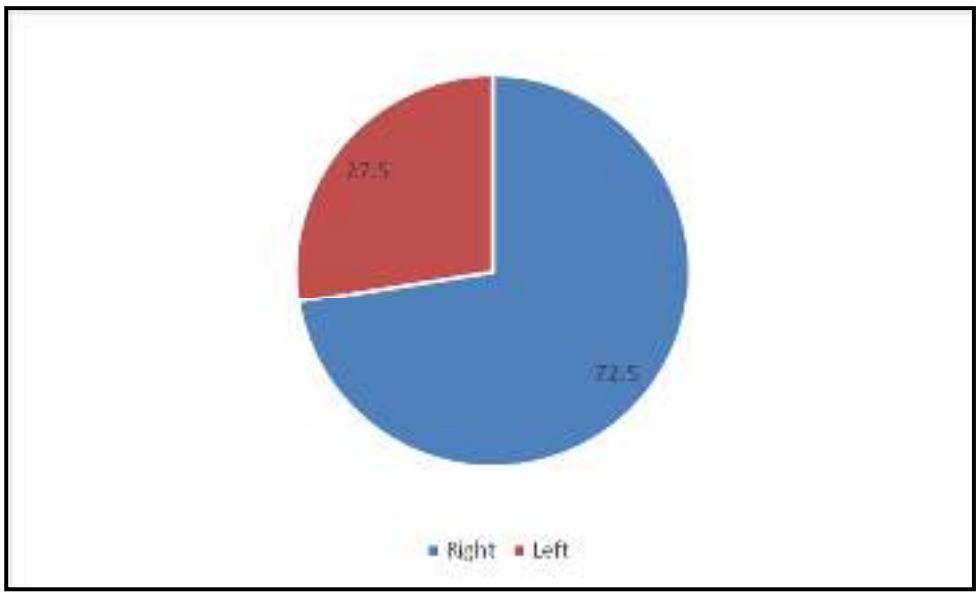


Figure no.2

Figure 2 shows the distribution of subjects based on side; 72.5% are right sided and 27.5% are left sided.

Gender Vs. Dominance

	Dominance		
	D	N	Total

Sex	Male	Frequency	19	2	21
		Percentage	90.5%	9.5%	100.0%
	Female	Frequency	16	3	19
		Percentage	84.2%	15.8%	100.0%
Total		Frequency	35	5	40
		Percentage	87.5%	12.5%	100.0%

Table no.2

Table 2 shows male dominant are 90.5 % and non dominant males are 9.5%;female dominants are 84.2% and female non dominants are 15.8 %.In total 87.5% are dominant sided and 12.5% are non dominant sided.

Distribution of subjects based on dominance

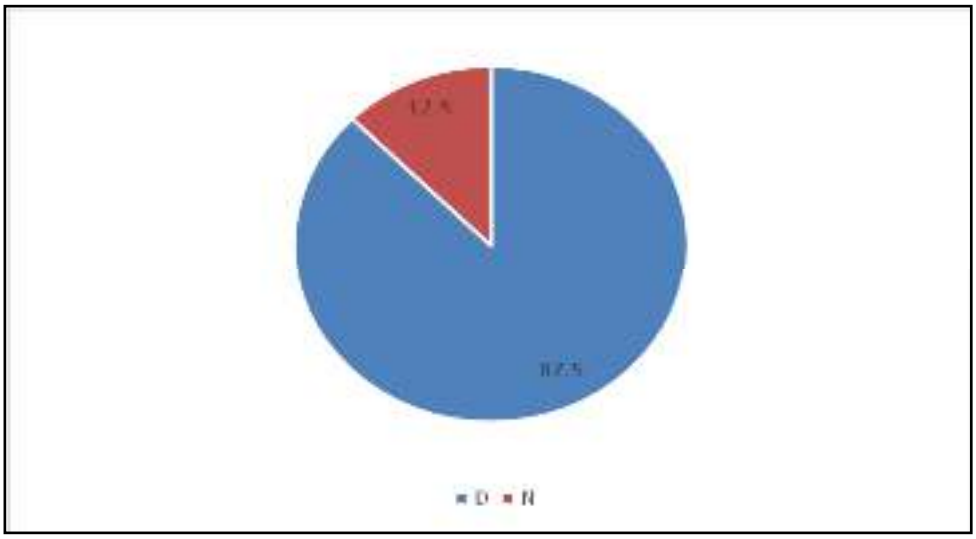


Figure no.3

Figure 3 shows 87.5% are dominant sided and 12.5% are non dominant sided.

Comparison of Age, duration and VAS scores among different gender

Dominance vs. side

			Dominance		
			D	N	Total
Side	Right	Frequency	26	3	29

		Percentage	89.7%	10.3%	100.0%
	Left	Frequency	9	2	11
		Percentage	81.8%	18.2%	100.0%
Total		Frequency	35	5	40
		Percentage	87.5%	12.5%	100.0%

Table no.3

Table 3 shows 89.7% are right sided dominant and 10.3% are right sided non dominant; 81.8% are left sided dominant and 18.2% are left sided non dominant. In total 87.5 % are dominant sided and 12.5% are non dominant sided.

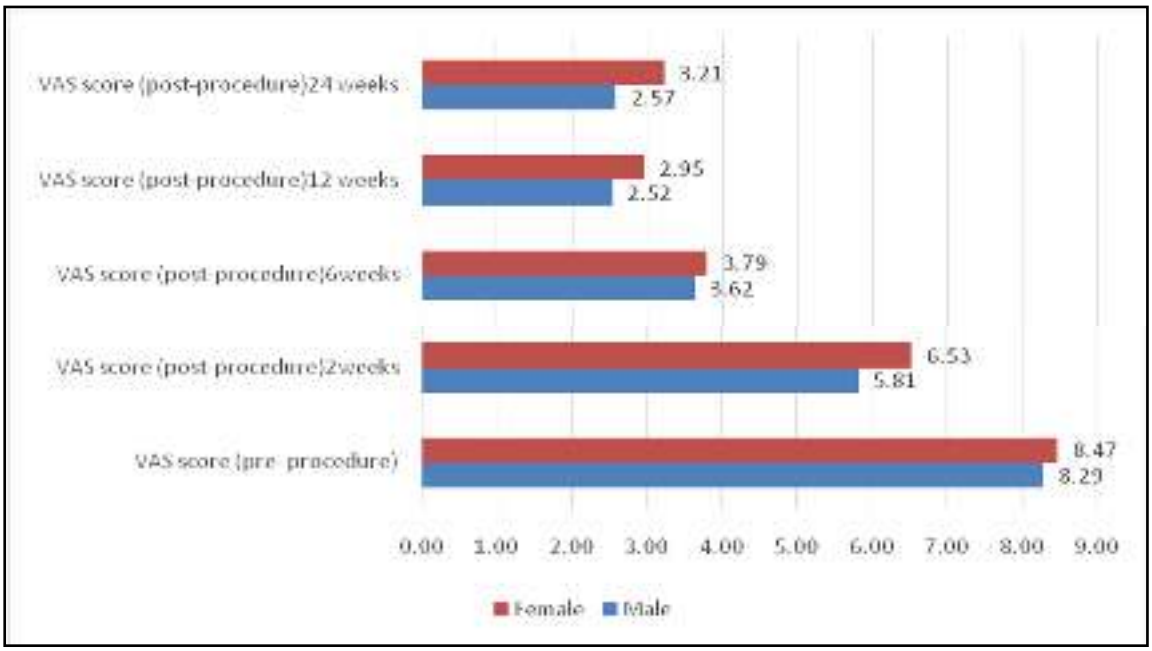


Figure no.4

Figure 4 explains about VAS score pre and post procedure in males and females. The pre procedure VAS score in males is 8.29,in females is 8.47. The VAS score post procedure at 24 weeks follow up is 2.57 in males and 3.21 in females.

Sex		N	Mean	Std. Deviation	P-value
Age	Male	21	44.5714	6.25757	.089
	Female	19	41.3684	5.21973	
Duration(wks)	Male	21	8.2857	5.64042	.152
	Female	19	6.2632	2.23214	
VAS score (pre-procedure)	Male	21	8.2857	1.00712	.571
	Female	19	8.4737	1.07333	
VAS score (post-procedure)2weeks	Male	21	5.8095	1.24976	.103
	Female	19	6.5263	1.46699	
VAS score (post-procedure)6weeks	Male	21	3.6190	1.49921	.731
	Female	19	3.7895	1.61861	
VAS score (post-procedure)12 weeks	Male	21	2.5238	1.40068	.441
	Female	19	2.9474	2.01311	
VAS score (post-procedure)24 weeks	Male	21	2.5714	1.66046	.286
	Female	19	3.2105	2.07040	

Independent t test
Table no.4

Table 4 shows the comparison of age, duration, VAS score of pre procedure and post procedure follow up at 2 weeks, 6 weeks,12 weeks,24 weeks among males and females. The mean age is 44.5 ±6.2 in males,41.3±5.2 in females; duration among males is 8.2±5.6 and among females is 6.2±2.2.The pre procedure VAS score in males is 8.2±1.0, in females is 8.4±1.07;VAS score post procedure follow up after 24 weeks is 2.5±1.66 among males , 3.2±2.07 among females.

Comparison of Age, duration and VAS scores based on side

Side	N	Mean	Std.	P-value

				Deviation	
Age	Right	29	43.2759	6.27294	.701
	Left	11	42.4545	5.18389	
Duration(wks)	Right	29	7.7241	4.98495	.362
	Left	11	6.2727	2.32770	
VAS score (pre-procedure)	Right	29	8.3448	1.07822	.768
	Left	11	8.4545	.93420	
VAS score (post-procedure)2weeks	Right	29	6.2759	1.36006	.358
	Left	11	5.8182	1.47093	
VAS score (post-procedure)6weeks	Right	29	3.7241	1.46132	.875
	Left	11	3.6364	1.80404	
VAS score (post-procedure)12 weeks	Right	29	2.6207	1.61276	.538
	Left	11	3.0000	2.00000	
VAS score (post-procedure)24 weeks	Right	29	2.5862	1.76306	.114
	Left	11	3.6364	2.01359	

Independent t test

Table no. 5

Table 5 shows the comparison of age, duration, VAS score of pre procedure and post procedure follow up at 2 weeks,6 weeks,12 weeks,24 weeks based on right and left side. The mean age is 43.2 ±6.2 in right sided patients,42.4±5.1 in left sided patients; duration among right sided patients is 7.7±4.9 and among left sided patients is 6.27±2.32.The pre procedure VAS score in right sided patients is 8.34±1.07, in females is 8.45±0.93 ;VAS score post procedure follow up after 24 weeks is 2.58±1.76 among right sided patients , 3.63±2.01 among left sided patients.

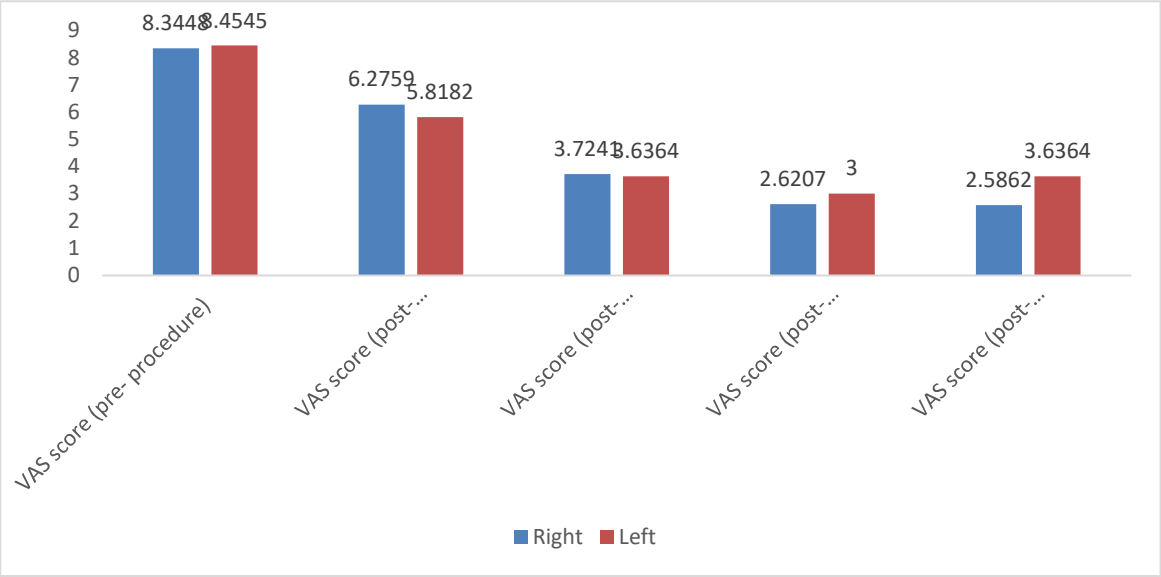


Figure no.5

Figure 5 explains about VAS score pre and post procedure in right sided and left sided individuals. The pre procedure VAS score in right sided individuals is 8.34, in left sided individuals is 8.45. The VAS score post procedure at 24 weeks follow up is 2.58 in right side individuals and 3.63 in left side individuals.

Comparison of Age, duration and VAS scores based on dominance

Dominance		N	Mean	Std. Deviation	P-value
Age	D	35	43.1714	6.12846	.737
	N	5	42.2000	4.86826	
Duration(wks)	D	35	7.6286	4.65318	.257
	N	5	5.2000	1.09545	
VAS score (pre-	D	35	8.3429	1.08310	.608

procedure)	N	5	8.6000	.54772	
VAS score (post-procedure)2weeks	D	35	6.1143	1.43017	.672
	N	5	6.4000	1.14018	
VAS score (post-procedure)6weeks	D	35	3.6857	1.51019	.879
	N	5	3.8000	1.92354	
VAS score (post-procedure)12 weeks	D	35	2.6857	1.65869	.706
	N	5	3.0000	2.23607	
VAS score (post-procedure)24 weeks	D	35	2.7429	1.85255	.242
	N	5	3.8000	1.92354	

Independent t test

Table no.6

Table 6 shows the comparison of age, duration, VAS score of pre procedure and post procedure follow up at 2 weeks,6 weeks,12 weeks,24 weeks based on dominance. The mean age is 43.17 ±6.12 in dominant sided patients,42.2±4.8 in non dominant sided patients; duration among dominant sided patients is 7.6±4.6 and among non dominant sided patients is 5.20±1.09.The pre procedure VAS score in dominant sided patients is 8.34±1.08, in non dominant side is 8.60±0.54 ;VAS score post procedure follow up after 24 weeks is 2.74±1.85 among dominant sided patients , 3.80±1.92 among non dominant sided patients.

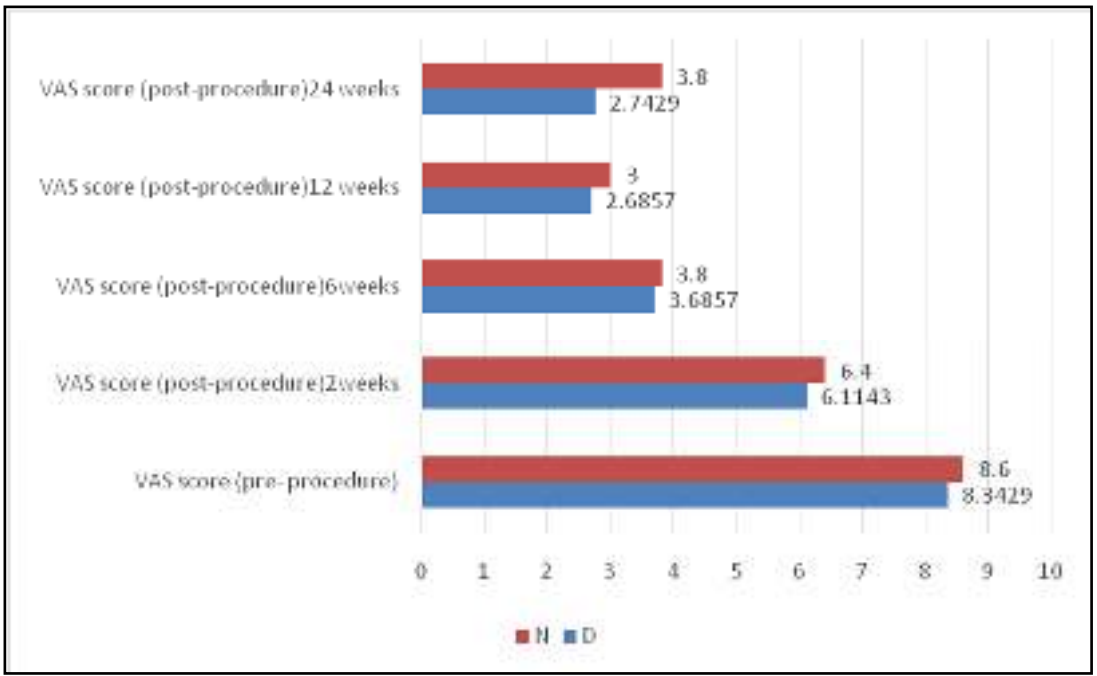


Figure no.6

Figure 6 explains about VAS score pre and post procedure in dominant sided and non dominant sided individuals. The pre procedure VAS score in dominant sided individuals is 8.34, in non dominant sided individuals is 8.6. The VAS score post procedure at 24 weeks follow up is 2.74 in dominant side individuals and 3.8 in non dominant side individuals.

Comparing the mean VAS scores among the subjects at different time points

VAS	Mean	Std. Error	95% Confidence Interval		P-value
			Lower Bound	Upper Bound	
Pre- procedure	8.375	1.03000	8.046	8.704	0.00
2weeks post-procedure	6.150	1.38767	5.706	6.594	
6weeks post-procedure	3.700	1.53923	3.208	4.192	

12 weeks post-procedure	2.725	1.70951	2.178	3.272	
24 weeks post-procedure	2.875	1.86997	2.277	3.473	

Repeated Measures ANOVA

Table no.7

This table shows mean VAS score at different time points , the mean VAS score pre procedure is 8.37±1.03 , mean VAS score post procedure at 24 weeks is 2.87±1.86 with p value of 0.001 which is infers very significant.

(I) factor1		Mean Difference (I-J)	p-value
Pre- procedure	2 weeks	2.225*	.000
	6 weeks	4.675*	.000

	12 weeks	5.650*	.000
	24 weeks	5.500*	.000
2 weeks	6 weeks	2.450*	.000
	12 weeks	3.425*	.000
	24 weeks	3.275*	.000
6 weeks	12 weeks	.975*	.000
	24 weeks	.825	.080
12 weeks	24 weeks	-.150	1.000

Post Hoc Bonferroni

Table no.8

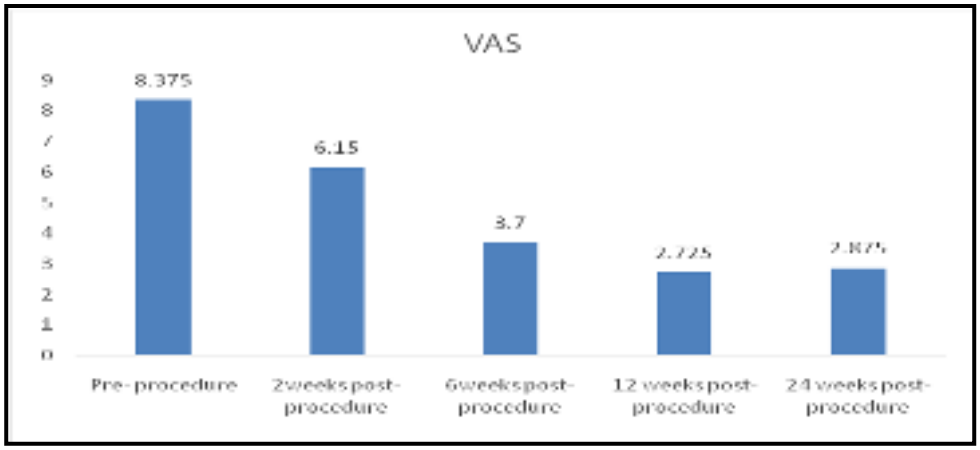


Figure no.7

The bar diagram shows the mean VAS score pre procedure is 8.37, at 2 weeks post procedure is 6.15 , at 6 weeks post procedure is 3.7 , at 12 weeks post procedure is 2.72 , at 24 weeks post procedure is 2.87.

Sex		N	Mean	Std. Deviation	p-value
NIRSCHL (pre-procedure)	Male	21	6.1429	.85356	.306
	Female	19	6.4211	.83771	
NIRSCHL (post-procedure)2weeks	Male	21	3.9048	.88909	.003
	Female	19	4.8421	1.01451	
NIRSCHL (post-procedure)6weeks	Male	21	2.6190	1.16087	.098
	Female	19	3.2632	1.24017	
NIRSCHL (post-procedure)12 weeks	Male	21	2.0952	.99523	.200
	Female	19	2.6316	1.57093	
NIRSCHL (post-procedure)24 weeks	Male	21	1.9524	1.24403	.190
	Female	19	2.5789	1.70996	

Independent t test

Table no.9

Table shows gender wise comparison of Nirschl score , the pre procedure scores are 6.14 ±0.83 in males, 6.42 ± 0.83 in females ; 24 weeks post procedure scores are 1.9 ± 1.24 in males, 2.5 ± 1.7

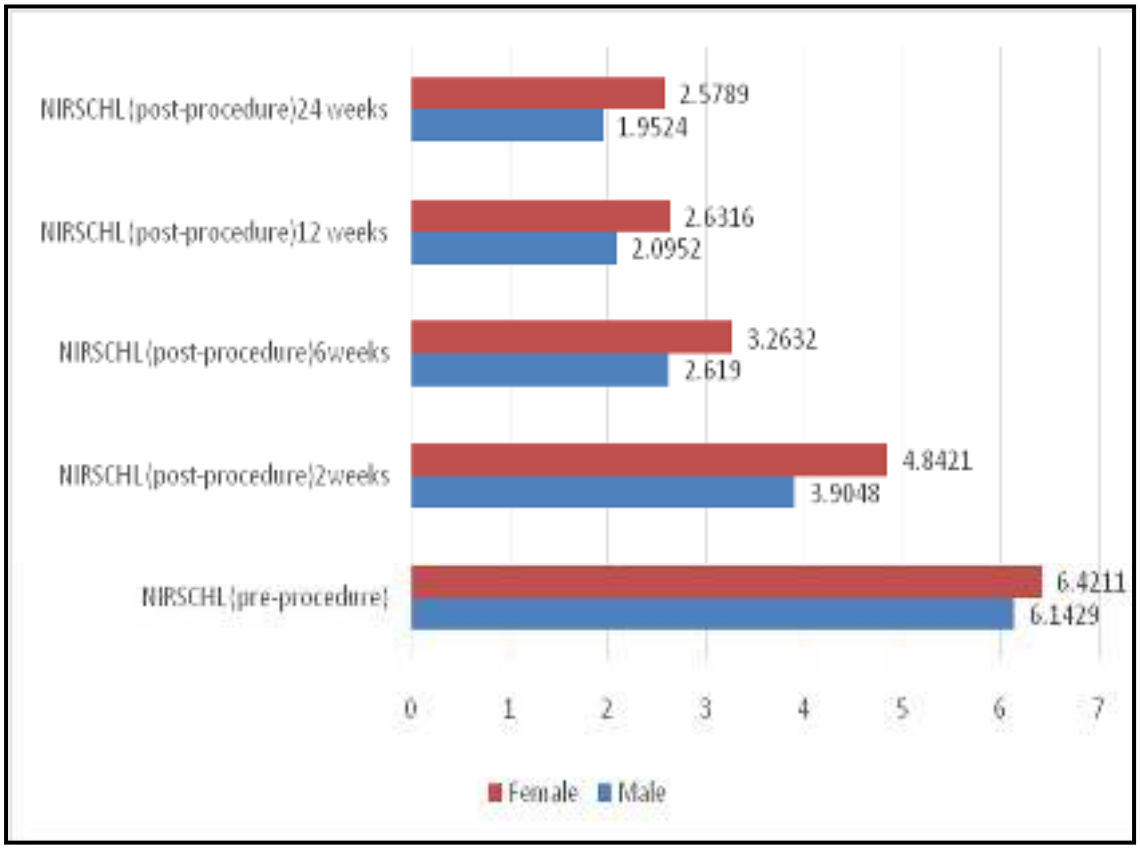


Figure no.8

Figure explains about gender wise comparison of nirschl score pre procedure and post procedure follow up, pre procedure scores are 6.42 in females and 6.14 in males ; 24 weeks post procedure scores are 2.57 in females and 1.95 in males.

Side		N	Mean	Std. Deviation	p-value
NIRSCHL (pre-procedure)	Right	29	6.2759	.92182	.992
	Left	11	6.2727	.64667	
NIRSCHL (post-procedure)2weeks	Right	29	4.2759	1.13063	.476
	Left	11	4.5455	.82020	
NIRSCHL (post-procedure)6weeks	Right	29	2.7586	1.27210	.167
	Left	11	3.3636	1.02691	
NIRSCHL (post-procedure)12 weeks	Right	29	2.2069	1.29227	.268
	Left	11	2.7273	1.34840	
NIRSCHL (post-procedure)24 weeks	Right	29	2.1724	1.46553	.601
	Left	11	2.4545	1.63485	

Independent t test

Table no.10

Table explains about the Nirschl score pre procedure and post procedure based on side; pre procedure scores are 6.27±0.92 on right sided patients and 6.27±0.64 on left sided patients; 24 weeks post procedure scores are 2.17 ± 1.46 on right sided patients and 2.4 ± 1.6 on left sided patients.

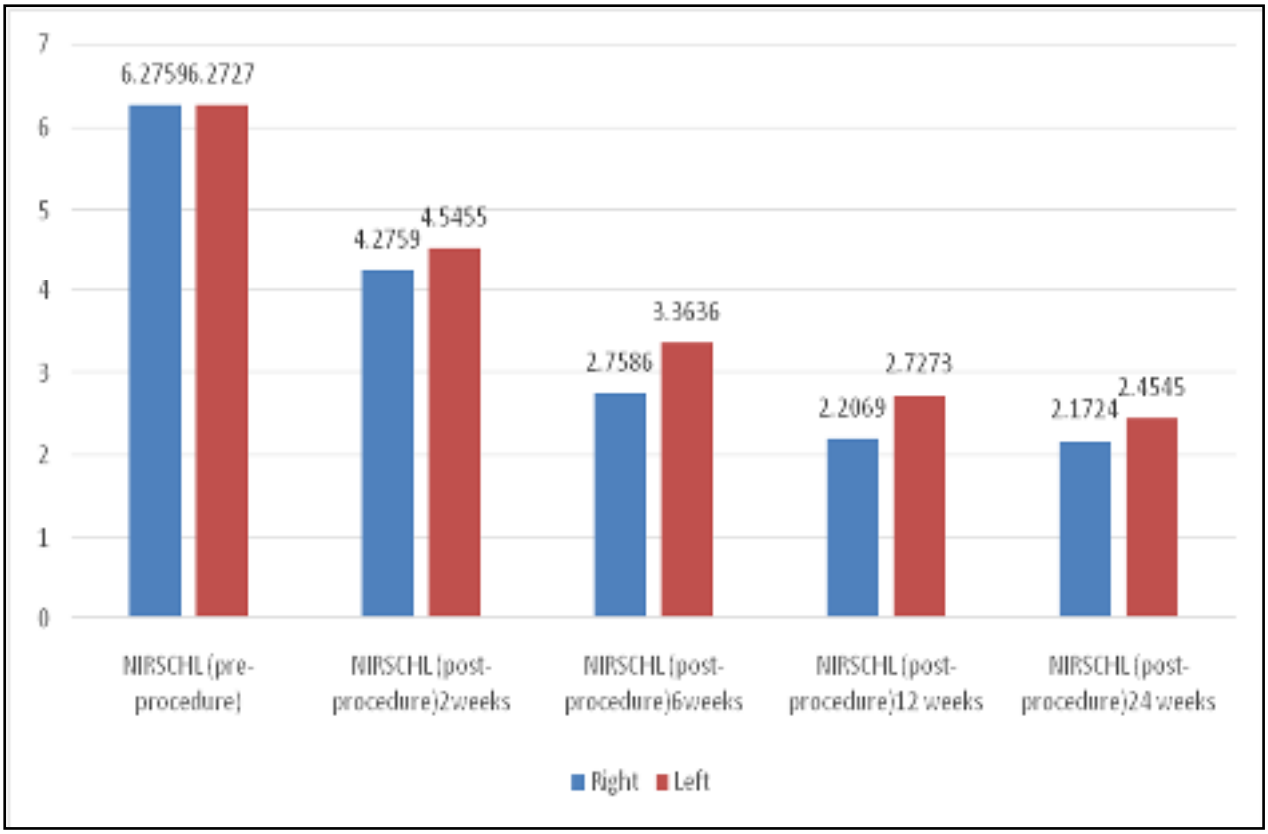


Figure no. 9

Figure shows nirschl score based on side pre procedure and post procedure; scores of right sided patients is 6.27 and 6.27 for left sided patients pre procedure , 24 weeks post procedure scores are 2.17 on right sided patients and 2.45 on left sided patients.

Dominance		N	Mean	Std. Deviation	p-value
NIRSCHL (pre-procedure)	D	35	6.2286	.87735	.366
	N	5	6.6000	.54772	
NIRSCHL (post-procedure)2weeks	D	35	4.3143	1.07844	.576
	N	5	4.6000	.89443	
NIRSCHL (post-procedure)6weeks	D	35	2.8571	1.16677	.362
	N	5	3.4000	1.67332	
NIRSCHL (post-procedure)12 weeks	D	35	2.2857	1.10004	.419
	N	5	2.8000	2.48998	
NIRSCHL (post-	D	35	2.1143	1.36708	.131

procedure)24 weeks	N	5	3.2000	2.16795	

Independent t test

Table no. 11

Table explains about the comparison of nirschl scores based on dominance ; pre procedure score of dominant handed patients is 6.22 ± 0.87 and non dominant handed patients is 6.6 ± 0.54 ; 24 weeks post procedure nirschl scores of dominant handed patients is 2.11 ± 1.36 and non dominant handed patients is 3.20 ± 2.16.

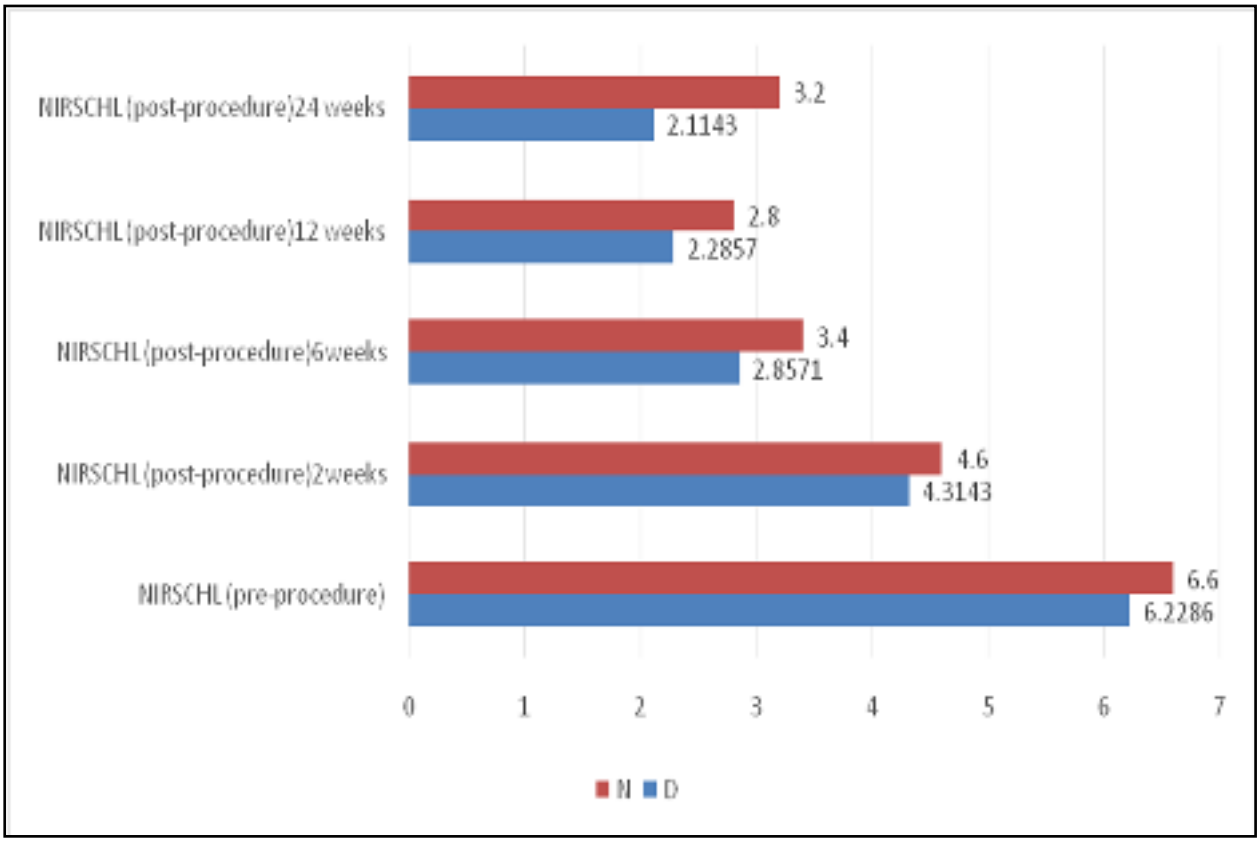


Figure no.10

Figure explains about the comparison of nirschl score based on dominance; pre procedure nirschl score in dominant hand is 6.22 and in non dominant hand nirschl

score is 6.6; 24 weeks post procedure nirschl score on dominant side is 2.11 and on non dominant side is 3.2.

NIRSCHL	Mean	Std. Error	95% Confidence Interval		P-value
			Lower Bound	Upper Bound	
Pre- procedure	6.275	.134	6.004	6.546	0.000
2weeks post-procedure	4.350	.166	4.014	4.686	
6weeks post-procedure	2.925	.194	2.532	3.318	
12 weeks post-procedure	2.350	.207	1.931	2.769	
24 weeks post-procedure	2.250	.237	1.771	2.729	

Repeated measures ANOVA

Table no. 11

Table explains about the mean Nirschl score pre procedure and post procedure, mean nirschl pre procedure score is 6.27, at 2 weeks follow up the nirschl score is 4.3, at 6 weeks follow up score is 2.9 , at 12 weeks follow up score is 2.35 , at 24 weeks follow up the score is 2.25 with the p value < 0.0001 which infers highly significant.

(I) factor1	Factor (j)	Mean Difference (I-J)	P-VALUE
Pre- procedure	2 weeks	1.925*	.000
	6 weeks	3.350*	.000
	12 weeks	3.925*	.000
	24 weeks	4.025*	.000
2 weeks	6 weeks	1.425*	.000
	12 weeks	2.000*	.000
	24 weeks	2.100*	.000
6 weeks	12 weeks	.575*	.003
	24 weeks	.675*	.033
12 weeks	24 weeks	.100	1.000

Post Hoc Bonferroni

Table no.13

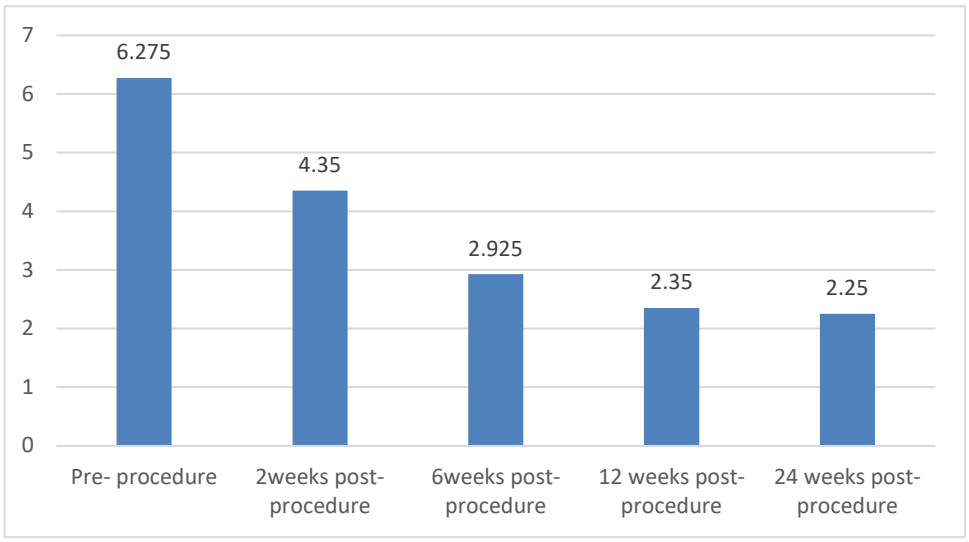


Figure no.11

Bar diagram explains about the mean nirschl score pre procedure and at subsequent post procedure follow ups. The pre procedure score is 6.27 , at 2 weeks score is 4.35 , at 6 weeks score is 2.92 , at 12 weeks score is 2.35 , at 24 weeks score is 2.25.

DISCUSSION:

Multiple micro traumatic episodes cause the tendon's internal structure to be disrupted, as well as the cells and matrix to degenerate and fail to grow into normal tendon, resulting in chronic overuse injuries such lateral epicondylitis. Despite the widespread usage of the word tendonitis to characterize the ailment caused by overuse, histopathologic investigations have revealed that tendons retrieved from regions of chronic overuse do not contain a substantial number of inflammatory cells. Tendoninosis, rather than tendonitis, appears to be a degenerative condition marked by large populations of fibroblasts, vascular hyperplasia, and disordered collagen. Angiofibroblastic hyperplasia is the name given to this group of symptoms[8].

In this study out of 40 individuals the mean age is 44.5±6.2 in males and 41.3±5.2 in females.

In this study out of 40 individuals, 29 (72.5%) were right handed and 11 (27.5%) was left handed. 35(87.5%) was dominant handed and 5(12.5%) was non dominant handed.

Another research by Edwards SG and colleagues found that 78.6 percent of people had problems with their dominant limb[8]. In a research done by Verhaar J, 84 percent of individuals with dominant elbow were affected[83].

The mean VAS score at the time of presentation based on side was 8.34 ±1.07 in right hand side and 8.45 ± 0.93 in left hand side. By the end of 24 weeks mean VAS score was 2.5±1.76 and 3.6 ±2.0 in right and left sided respectively.

The mean VAS score at the time of presentation based on gender was 8.28±1.0 in males and 8.47 ±1.07 in females. By the end of 24 weeks mean VAS score was 2.5±1.66 and 3.2 ±2.07 in males and females respectively.

The mean VAS score based on dominant side pre procedure was 8.3 ±1.08 on dominant side and 8.6 ± 0.5 on non dominant side and the VAS score by the end of 24 weeks follow up has come down to 2.7±1.8 on dominant side and 3.8±1.9 on non dominant side.

The mean VAS score at the time of presentation with p value <0.001 was 8.3 and 2.8 at 24 week follow up.

Edwards and Calandruccio et al. conducted a similar investigation. Post autologous blood injection therapy, 22 of 28 patients (79 percent) were pain-free even during heavy exercise, and their VAS score improved from 7.8 to 2.3[8].

After six weeks, injections were reported to be successful by 78 percent of subjects, compared to 65 percent for physiotherapy with RRR 0.4 (99 percent CI 0.2 to 0.9) and 27 percent for wait and watch with RRR 0.7, according to Bisset et al (99 percent CI 0.4 to 0.9)[84].

The autologous blood injection group had a statistically significant lower pain level than the corticosteroid injection group at the 12-week and six-month follow-ups, according to a recent study comparing the effectiveness of local corticosteroid and autologous blood injection for lateral epicondylitis[38].

Smidt et al. analyzed thirteen randomized controlled trials on the use of local corticosteroid injections in tennis elbow and found that when compared to placebo, local anesthetic, and conservative treatment, local corticosteroid injections provide superior benefit (pain, global improvement, and grip strength) in the short-term (6 weeks). The intermediate (6 weeks-6 months) and long-term (6 months) effects, however, were not sustained. The mechanism of short-term relief caused by steroid injections is unclear[85]. Bleeding into the degraded region through fenestrations created by needling, on the other hand, might be the reason.

In contrast to the literature, Wolf et al. concluded that ECRB tendinopathy is self-limiting and found no advantage from autologous blood injection over corticosteroid or saline injection. We did the study in a cohort of resistive patients to rule out the potential of self-limitation since lateral epicondylitis can be self-limited in certain people[86].

The mean Nirschl score at the time of presentation based on side was 6.27 ± 0.92 in right hand side and 6.27 ± 0.64 in left hand side. By the end of 24 weeks mean

Nirschl score was 2.17 ± 1.46 and 2.45 ± 1.63 in right and left sided respectively.

The mean Nirschl score at the time of presentation based on gender was 6.14 ± 0.85 in males and 6.42 ± 0.83 in females. By the end of 24 weeks mean Nirschl score was 1.95 ± 1.24 and 2.57 ± 1.70 in males and females respectively.

The mean Nirschl score based on dominant side pre procedure was 6.22 ± 0.87 on dominant side and 6.60 ± 0.54 on non dominant side and the Nirschl score by the end of 24 weeks follow up has come down to 2.11 ± 1.36 on dominant side and 3.20 ± 2.16 on non dominant side.

The mean Nirschl score in 40 individuals pre injection with p value <0.0001 was 6.27 and mean Nirschl score at 24 weeks was 2.25.

Mahmood Karimi Mobarakeh et al. conducted a research in which 29 individuals with tennis elbow were treated with ABI (autologous blood injection). The average age of the patients was 44.15.2 years. Six months following therapy, VAS (Visual Analogue Scale) pain dropped from 6.46 2.08 to 0.54 0.7 (P=0.001), and NPS (Nirschl phase score) pain fell from 6.15 1.48 to 0.54 0.76 (P = 0.001). 84 percent of patients expressed high levels of satisfaction towards the end of the trial[32].

Plazcek et al. looked into the use of Botulinum A toxin injections and discovered that they provided considerable pain alleviation. They noticed substantial weakening in the third finger's extensor action, although none of the patients missed work as a result of it[87].

The mechanism of action for both autologous blood and platelet rich plasma is assumed to be the degranulation of platelet granules, which releases growth factors that help in tissue repair and regeneration. Platelet derived growth factor, transforming growth factor β, vascular derived endothelial growth factor, epithelial

growth factor, hepatocyte growth factor and insulin like growth factor are some of the factors involved[88].

According to Jindal et al., the relative concentration of platelets in platelet rich plasma (PRP) is 2.5 to 5 times greater than in blood. PRP appeared to be more effective than autologous blood in one clinical study due to a greater concentration of growth factors per unit volume. Platelet concentrates, on the other hand, need specialized equipment that is both expensive and time-consuming to make. As a result, platelet rich plasma (PRP) is far more difficult to work with than autologous blood[89].

In this study out of 40 samples, 36 patients had pain relief and were able to do their daily routine activity, 4 (10%) patients started having pain after injecting local autologous blood .

CONCLUSION:

One of the most frequent upper limb conditions that orthopedic surgeons see is lateral epicondylitis.

The most common age range for lateral epicondylitis was 30 to 55 years old.

In this study, men and women were almost equally impacted.

The underlying pathophysiology of lateral epicondylitis has been the subject of much controversy in the past.

A micro-tear at the beginning of extensor carpi radialis brevis is the current mechanism.

Lateral epicondylitis is no longer an inflammatory condition, according to microscopic examination. It is currently thought to be the result of a degenerative etiology.

Conservative and surgical therapy options are available.

Rest, cold application, and steroid injection are the most widely used conservative treatments.

In our study, Autologous blood is used and patients were followed up for 24 weeks.

In this study 36 (90 %) of patients had complete pain relief and had an improved daily life activities.

This study concludes that the autologous blood injection shows encouraging results in pain relief and improved active daily life in lateral epicondylitis cases. ABI is a safe, cost effective and very efficacious.

SUMMARY

This was a prospective observational research with 40 participants.

In situations of lateral epicondylitis, the effectiveness of autologous blood injection was discovered.

The VAS score and NIRSCHL staging were used to examine the patients clinically.

Patients were checked for pain alleviation at 2 weeks, 6 weeks, 12 weeks, and 24 weeks.

The VAS score and NIRSCHL staging were used to evaluate the outcomes.

Mann-Whitney U-test and T-test For the purpose of calculating outcomes, the U test is used.

At the 24-week follow-up, there was a considerable reduction in pain.

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INFORMED CONSENT

Title of the study “clinical evaluation of functional outcome in lateral epicondylitis by local injection of autologous blood”
Principal investigator: Dr. B.Vihasit

Guide: Dr. Dinesh.R.Kale

Introduction and purpose: Lateral epicondylitis or tennis elbow commonly encountered in orthopaedic practice. It has been found to be the most frequently diagnosed musculoskeletal disorder in the neck and upper extremity.

Incidence of 4-7 per 1000 per year in general practice, peak of incidence between 35 to 55 years age group. Dominant arm more prone than non dominant arm. It’s characteristic finding is pain over the lateral epicondyle. This is due to overuse of common extensor.

Presently degeneration of extensor tendon origin commonly extensor carpi radialis brevis, repeated micro trauma and incomplete healing response has been accepted as the cause of lateral epicondylitis.

Histopathology reports shown that lateral epicondylitis is not an inflammatory process but a degenerative condition called as tendinosis. There are various treatment modality conservative and operative. Conservative management includes local corticosteroid injection and platelet rich plasma are included in this study. Recent study shows long term good outcomes shown with platelet rich plasma.

Procedure: Once the patient signs in the informedconsent .History and examination to be recorded as per the proforma. Patients with symptoms typical to lateral epicondylitis who were clinically diagnosed to have tennis elbow. The patients will be given autologous blood. The results were recorded by visual analogue scale (VAS) score and NIRSCHL scoring

Benefits:

1.Relief of pain and improvement of function of elbow joint.

RISKS:

1. Infection.
2. Injury to surrounding structures.

Voluntary participation/ withdrawl:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The investigator or the sponsor may stop my participation in this study. I will tell of any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study, I will receive the standard treatment for patients with my condition.

Compensation:

As the subject voluntarily consents to be a part of the study, no compensation will be given.

Confidentiality:

All information collected about the subject during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify the subject in this research record. Information from this study may be presented but the subjects identity will be confidential in any publication.

If any enquiries in the future or in case of study related injury or illness, you may contact following person:

DR.B VIHASIT

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Department of Orthopaedics,
J.N. Medical College,
Belagavi - 590010
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In case you need any further information regarding your rights as study participant you may contact.

DR. ROOPA BELLAD
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Chairperson,
JNMC Institutional Ethics Committee
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Guide:
Dr.Dinesh.R.Kale, M.S. (Ortho),
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Dept. Of Orthopaedics,
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Belagavi –590010.

Consent to participate in research study:

"I voluntarily agree to take part in this study, platelet rich plasma versus corticosteroid for treatment of lateral epicondylitis by signing below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicates that I have read this entire consent form or it has been read to me, and had all my questions answered. I will be given a copy of this consent form." Signature of the participant or legally authorized representative.

Participant's Name: …….

Signature: …….

Name of the legally authorized representative: …….

Signature: …….

Witness's Name: …….

Signature: …….

Investigators name and Signature: …….

Date: ……. Place: …….

PROFORMA

"CLINICAL ASSESSMENT OF FUNCTIONAL OUTCOME IN LATERAL EPICONDYLITIS BY LOCAL INJECTION OF AUTOLOGOUS BLOOD"

Patient No : IP No:
Name:
Age: Sex:
Address:
Occupation:
DOA: DOS: DOD:
Chief Complaints:

Presenting Complaints:
Pain
Swelling
Difficulty in turning key
Inability to grip objects
Others

History Of Present Illness:
Pain: Site right/left side lateral epicondyle
Dominant or Non Dominant side
Onset : Sudden/Gradual
Nature : Continuos/Intermittent
Radiation: Present/Absent
Type of pain : Dull Aching/Burning Pain/Localised/Diffuse
Mode of onset: Repitive Pronation/Supination,Turning Keys And Turning Screw Driver
Any other complaints

Significant past history: 1- Yes 2- No

a. History of diabetes

b. Hypertension ☐

c. Asthma ☐

d. Previous history of injury around elbow joint ☐

e. Hypothyroidism ☐

f. Hyperthyroidism ☐

g. Cervical spondylosis ☐

h. Any associated disease ☐

Personal History:
Diet : Veg/ Mixed/ Nonveg
Appetite : Increased or Decreased
Habits : Smoking/ Alcohol /Tobacco chewer / others
Bowel & Bladder Habits: Normal or Abnormal

Family History:

General Physical Examination:
Built : Well/Moderate/Poor
Temperature: Pulse:
Blood Pressure: Respiratory Rate:
Pallor
Cyanosis
Icterus
Clubbing
Pedal edema
Lymphadenopathy

Systemic Examination:
Cardiovascular System Examination:
Respiratory System Examination:
Per Abdomen Examination:
Central Nervous System Examination:

Local Examination:

Examination of elbow : 1-Right 2-Left

On inspection:
Attitude of the limb _____
Local swelling
_____
_____
Skin over the elbow joint: _____
_____
Deformity: _____
_____
Muscle wasting: _____
_____

Palpation:
Local rise of temperature – present/absent
swelling: present/absent
Exact point of tenderness:
bony irregularity:present/absent
Movements

Range of movements	active	passive
Flexion		
Extention		
Supination		
Pronation		

Special tests : 1-positive 2- negative
Cozen Test: ☐
Mills test: ☐
Clinical diagnosis:
_____

Relevant Investigations:
1- Done 2- Not done
X-ray Elbow joint - Antero Posterior view ☐

- Lateral view ☐

Hb%, TLC, DLC, ESR, RBS ☐

Urine : Albumin, Sugar, Microscopy ☐

Complications:
1.Elbow Instability
2.Capsular Pathology
3.Bursitis
4.Capsular Fistula

Outcome Measure:-

1) Visual Analogue Scale (VAS):

	Pre Intervention	**2Weeks**	**6 Weeks**	**3 months**	**6 months**
VAS					

2)Nirschl Scoring
Phases Of Pain:

Benign Pain

Phase 0: No pain or soreness

Phase 1: Stiffness or mild soreness after exercise activity. Pain is usually gone in 24 hours.

Phase 2: Mild stiffness and soreness before activity which disappears with warm up. No pain during activity, but mild soreness after activity that disappears within 24 hours.

Phase 3: Same as above with mild pain during activity which does not alter activity, disappearing in 24-48 hours. Counterforce bracing may be considered here as well as mild anti-inflammatory medication.

Phase 4: Mild to moderate pain before, during, and after exercise which alters the exercise or activity. ADLs are affected. Phase 4 is indicative of some level of tendon damage.

Phase 5: Moderate or greater pain before, during, and after exercise or activity,

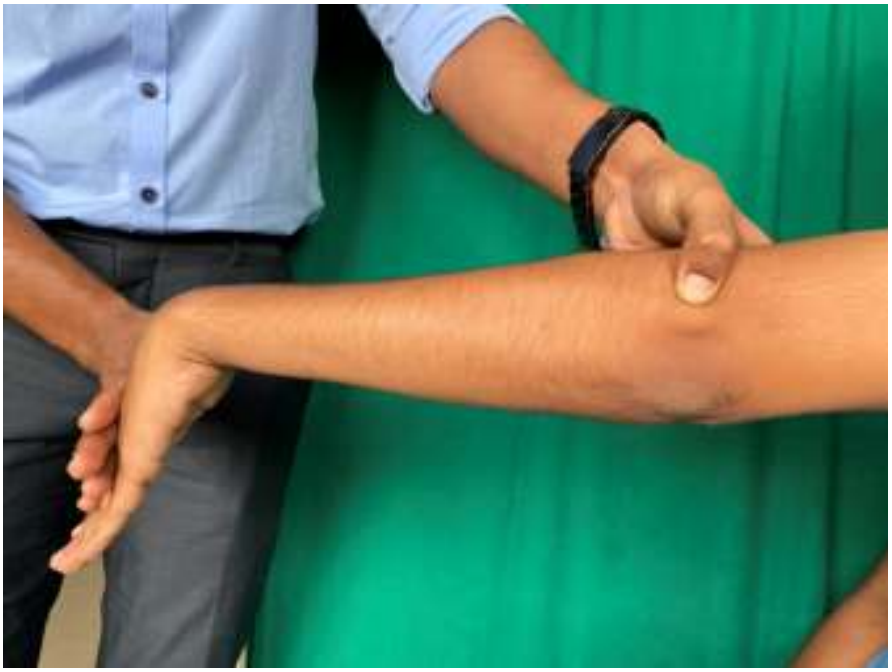
forcing the patient to discontinue the exercise. Pain is experienced with ADLs. Usually reflects permanent tendon damage

Phase 6: Phase 5 pain that persists with complete rest. Pain disrupts ADLs, many activities have to be eliminated.

Phase 7: Phase 6 pain with disruption of sleep on a consistent basis. Pain is aching in nature and intensifies with activity.

Pain phases 5, 6, and 7 indicate increasing percentages of permanent tendon damage.

PHOTOGRAPHS:



Photograph no.1 :Performing Mill's test

Photograph no.2: Performing cozen’s test

Photograph no.3: Injecting autologous blood.

Key to Master Chart:

ABI – Autologous blood injection
Sl.no – Serial number
M – Male
F – Female
D – Dominant
N – Non dominant
VAS – Visual Analogue Scale

AUTOLO						
Sl.No	**OP No.**	**Age**	**Sex**	**Side**	**Dominance**	**Duration(**
1	4229977	42	M	R	D	5
2	5330149	40	M	R	D	24
3	5745131	34	M	R	D	24
4	799385	45	M	R	D	7
5	3594568	55	M	R	D	9
6	5276970	48	M	R	D	12
7	1625249	45	M	R	D	3
8	5468335	30	F	R	D	4
9	2195663	47	F	R	N	6
10	5667361	34	M	R	D	6
11	5168687	52	M	R	D	6
12	4922878	53	M	R	D	5
13	4682104	45	F	R	D	8
14	4948990	38	F	R	D	7
15	4725564	36	M	L	N	6
16	4923153	35	F	L	D	5
17	4789932	39	F	R	D	6
18	4923150	38	M	L	N	6
19	4789928	36	M	R	D	6
20	4725503	46	M	R	D	8
21	4789949	42	F	L	D	3
22	4725620	49	M	L	D	4
23	5768740	48	F	L	D	6
24	5165256	46	F	R	D	5
25	4948989	45	M	L	D	4
26	4923020	43	M	R	D	9
27	4789727	48	M	R	D	10
28	4682097	44	F	L	D	11
29	4726657	49	M	R	D	8
30	5168671	50	F	L	D	8
31	4948995	35	F	R	D	9
32	5161827	49	M	R	D	6
33	4492799	41	F	R	D	4
34	5145950	40	F	L	D	8
35	4960997	45	F	R	N	4
36	5048995	35	F	R	D	9
37	5161093	49	M	R	D	6
38	4492768	41	F	R	D	4
39	5745905	40	F	L	D	8
40	5448997	45	F	R	N	4

VAS score (pre- procedure)	VAS score				NIRSCHL (pre-procedure)
	2weeks	6weeks	12 weeks	24 weeks	
9	7	4	2	0	6
8	5	3	1	1	6
9	6	5	0	1	7
10	7	4	2	4	7
8	7	6	4	3	6
7	6	3	3	4	5
8	5	3	2	3	6
7	6	3	0	0	5
9	6	4	2	3	7
10	6	2	3	2	7
8	5	2	2	2	6
9	6	5	2	4	7
7	6	3	2	2	5
6	5	3	2	3	5
8	6	2	2	3	6
9	7	5	3	3	7
9	6	2	2	3	7
8	5	3	2	4	6
7	7	6	7	7	5
9	6	2	2	3	7
8	4	3	2	2	6
8	4	3	2	2	6
7	7	6	7	7	5
8	3	2	1	1	6
8	4	2	2	3	6
7	4	2	2	3	5
6	4	3	3	3	4
9	5	2	2	2	7
9	6	4	2	0	7
8	8	7	7	8	6
9	8	5	3	2	7
9	8	6	4	2	7
9	8	3	4	4	7
10	7	5	2	3	7
9	7	3	2	2	7
9	8	4	2	2	7
9	8	6	4	0	7
9	8	3	4	4	7
10	7	2	2	3	7
9	8	7	7	7	7

NIRSCHL			
2weeks	**6weeks**	**12 weeks**	**24 weeks**
3	2	2	0
3	1	1	1
4	2	2	1
4	1	1	3
4	3	2	2
3	2	2	3
3	1	1	2
4	2	2	0
4	3	1	2
4	2	2	3
3	2	1	1
5	3	1	3
4	3	1	2
3	2	1	2
4	4	3	2
5	4	3	2
4	3	2	2
4	2	1	3
4	5	5	5
4	2	2	2
5	4	3	1
4	2	2	1
5	4	5	5
4	2	2	2
4	3	3	2
3	3	2	2
3	3	3	2
3	2	1	1
4	3	2	0
6	5	5	6
6	4	2	2
6	5	3	3
6	2	3	3
5	4	2	2
5	2	2	2
6	5	3	3
6	4	3	0
6	2	3	3
5	3	2	2
6	6	7	7
