

Efficacy of a local corticosteroid injection on pain, disability and radial nerve thickness in patients with lateral epicondylitis

Abhimanyu Vasudeva¹, Ritika Parihar², Osama Neyaz³, Ajay Bharti⁴,
Gita Handa²

Departments of ¹Physical Medicine and Rehabilitation, ⁴Orthopedics, All India Institute of Medical Sciences, Gorakhpur, Uttar Pradesh, ²Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, New Delhi, ³Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, India

ABSTRACT

Introduction: The aim of this study was to compare the effect of a steroid injection with conservative therapy (CT) versus CT alone on pain, functional limitations and the cross-sectional area (CSA) of the radial nerve (RN) in patients with lateral epicondylitis (LE). **Methods:** In this clinical trial, seventy subjects in the age group of 30–60 years with a clinical diagnosis of LE were recruited. Patients received an ultrasound-guided steroid injection and CT (Group A, $n = 35$) or CT alone (Group B, $n = 35$). Pain intensity (numeric pain rating scale), functional limitations (Quick Disabilities of the Arm, Shoulder, and Hand questionnaire) and the CSA of RN (mm^2) using ultrasound were assessed at baseline, 4 and 12 weeks. **Results:** There was a significant difference in pain intensity ($P < 0.05$) at 4 weeks in favour of Group A but not at 12 weeks. A statistically significant difference was not present favouring either group concerning disability at both the follow-ups. The difference in CSA of the RN at the affected side in both groups A and B was not statistically significant at either the spiral groove or the antecubital fossa at baseline or the subsequent follow-ups. **Conclusions:** The CT with a steroid injection proved to be more efficacious in the short term concerning pain intensity and functional limitations. The RN thickness is not increased in patients with LE, thereby refuting its role to some extent in the pathogenesis of LE.

Keywords: Functional limitation, lateral epicondylitis, pain, radial nerve, tennis elbow

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Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, New Delhi – 110029, India.

Address for correspondence: Dr. Osama Neyaz, Assistant Professor, Department of Physical Medicine and Rehabilitation, All India Institute of Medical Sciences, Rishikesh, Uttarakhand, Pin Code – 249 203, India.
E-mail: osamaneyaz@gmail.com

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Introduction

Lateral epicondylitis (LE), also known as tennis elbow or tendonitis of the extensor muscles of the forearm, is a common problem with a prevalence of 1–3% in the general population.^[1] Clinical findings are used to make the diagnosis of LE. Imaging is a useful supplement.^[2] The most common implication of the extensor tendons is the extensor carpi radialis brevis. However, traditionally thought of as an inflammatory process, a more recent histological examination suggests LE is tendinosis.^[3] Two commonly used therapies for LE are a conservative approach and

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local steroid injections.^[4] Patients with LE are usually seen by their primary care physician first. They play an essential role in disease management, particularly in rural areas. Shared decision-making is gaining traction in the delivery of patient-centred care by taking current evidence-based practice findings as well as the patient's values, desires, and preferences into account.^[5]

A theoretical framework noting that the nervous system is likely one component in causing pain in LE emphasized that the excessive expansion of neuronal action and the loss of homeostatic regulation by RN-derived nociceptors contribute to axonal growth free sensitive spots.^[6] The present study's focus was not on radial nerve (RN) compression or entrapment neuropathy as the primary driver of the pathophysiology but the RN's role in peripheral sensitization.

However, no clinical evidence exists for the RN's role as a contributory etiologic factor in LE. This, alongside growing evidence of peripheral and central sensitization, without the RN's specific role in LE cases, prompted us to look at the RN as an additional objective of this study to see if the theoretical framework described by Bordachar *et al.*^[6] holds promise.

The ideal way to understand the pathogenesis would be to do electrophysiological tests to understand the physiological changes, histopathology of various structures to look for abnormalities in the tissues and nerves, and an array of tests to understand the biochemical milieu at the nerve–muscle junction. Understanding so many moving parts needs to be done separately as many studies have focused on aspects other than the RN; it was decided to focus on RN only in this study. The RN being the afferent supply from the common extensor tendon and relaying information to the spinal cord is the central piece in this chain, and the focus to visualize it using non-invasive means such as ultrasonography (USG) is one of the most feasible ways to understand its contribution to the pathogenesis.

Non-invasive options such as USG in expert hands can give us a reasonably good picture of the RN and, by that count, the involvement of the RN's tenuous role in the pathophysiology. This can also be routinely done at follow-ups.^[7]

The primary objectives were to compare the effect of a steroid injection with conservative therapy (CT) versus CT alone on pain using a numeric pain rating scale (NPRS) and functional limitations using Quick Disabilities of the Arm, Shoulder, and Hand questionnaire (q-DASH) and ultrasonographic measurement of the cross-sectional area (CSA) of the RN in patients with LE. The secondary objective was to correlate functional limitations using q-DASH scores with ultrasonographic measurement of the RN's CSA in patients with LE. The differential response of the above two treatment approaches on the RN's CSA and its correlation with pain and functional improvement in patients with LE at follow-ups need to be seen to elucidate the pathogenesis further.

Methodology

This is a prospective, randomized controlled study. The patients were randomized in a 1:1 ratio into the local steroid injection plus conservative treatment (Group A) and conservative treatment alone (Group B). Patients diagnosed with LE based on clinical examination after filling informed written consent forms (in Hindi and English) and screened for the eligibility criteria were included. All the enrolled patients were given conservative treatment for 4 weeks and subsequently re-assessed based on the NPRS score. Participants who completed 4 weeks of conservative treatment and had NPRS between 4 and 7 were randomized into Group A or B.

Patients in the age group of 30–60 years, either gender, clinical diagnosis of LE,^[8] or having an NPRS score between 4 and 7 after 4 weeks of conservative management as per a predefined protocol^[9] were included. Subjects with a history of previous treatment for ipsilateral LE, other elbow pathologies, cervical vertebrae/upper limb disorders, previous elbow surgery, joint limitations due to any prior radius/ulna fracture, osteoporosis, malignancy, haemophilia; any clinical finding suggestive of peripheral nerve (ulnar, radial, median) disease; mechanical symptoms (locking, clicking, limited motion) of the elbow including joint limitations following radius/ulna fracture; local infection at the site of injection or generalized infection; prior steroid injection in the same elbow; known allergy to steroid; a history of trauma around elbow; contraindication of steroid (uncontrolled hypertension, diabetes and pregnancy, breastfeeding); bilateral LE; and refusing to participate in the study were excluded.

The study was conducted in the Department of Physical Medicine and Rehabilitation (PMR) at a tertiary hospital in India. It commenced after approval from the ethics committee (approval no. IECPG/322/6/2017) and subsequent registration in the clinical trials registry of India (CTRI/2018/03/012824).

The information gathered from a detailed history, including the demographic profile, was recorded; thorough clinical examination findings were noted. Haemoglobin, total leucocyte count, differential leucocyte count, erythrocyte sedimentation rate, fasting blood sugar, postprandial blood sugar and a plain radiograph of the elbow joint anteroposterior and lateral views were obtained from each patient.

Intervention

Patients in Group A received a local injection of 40 mg of methylprednisolone acetate under USG guidance and conservative management, whereas group B received conservative management alone.

The conservative treatment included tablet Aceclofenac 100 mg if required and tablet Pantoprazole 40 mg if needed; rest from repetitive activities aggravating pain, deep friction massage, ice application, stretching exercises, grip strengthening and

counterforce bracing.^[6] Conservative management was continued throughout the study period irrespective of the management response.

In Group A, patients were injected supine with the elbow flexed at 90° raised and resting on a cushion with the forearm in pronation. The skin around the lateral epicondyle and injection site was cleaned with antiseptics. A USG-guided 40 mg of methylprednisolone acetate was injected using a disposable needle (23 G, 2 cm) and a syringe (1 ml) at the insertion of extensor digitorum brevis under aseptic precautions, at the tissue plane between the subcutaneous fat and the tendon (no local anaesthetics were used). Lastly, the needle was withdrawn, and the pad and bandage were applied.

Participants were observed for 30 min following injection and advised to rest the injected arm for 48 h and avoid all strenuous activity for 1–2 weeks following injection, followed by a gradual return to normal activities. No additional medications were advised except for cold compresses and tablet Aceclofenac for pain relief as and when required basis for 1 week. After this, further treatment approach in the two groups was similar. Patients were advised to keep a diary for counting pills taken during the study period, that is, until the last follow-up visit. Group B received conservative treatment alone.

The patients were advised to report any serious adverse events during the study period, and these were noted. The patients were free to withdraw from the study at any time; this would not have affected the standard of care and treatment they received.

Outcome measures

The NPRS score was used for the assessment of pain intensity. The patient indicates the intensity of pain levels over the past 24 h on a scale of 0 (no pain) to 10 (worst pain imaginable).^[10] The q-DASH is a shortened version of the original DASH scale. The q-DASH was designed to be helpful in patients with any musculoskeletal disorder of the upper limb and is a valid and reliable scale. It is a questionnaire that involves a subset of 11 items from the 30-item DASH, and the response options are presented as 5-point Likert scales. The scores range from 0 (no disability) to 100 (most severe disability).^[11] The scale was translated into the regional language by a linguist expert for patients facing difficulty understanding the English version.

The USG measurement of the RN's CSA was assessed using My Lab One ultrasound device (Model 8100, Esaote, Japan) with B-mode imaging. The measurement was taken in sitting positions with the arm supported, forearm pronated, and moderate elbow flexion. The CSA of RN was measured at the spiral groove (SG) and the antecubital fossa (AF) before branching into the superficial radial and posterior interosseous nerves^[7] in mm² on the affected and the unaffected sides [as shown in Figures 1 and 2]. A PMR specialist took all measurements with more than 5 years of experience in musculoskeletal USG. The unaffected side was

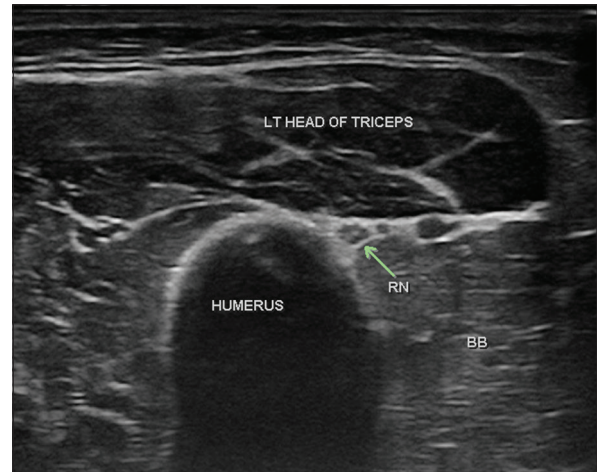


Figure 1: The radial nerve at the spiral groove of the humerus. Footnote to Figure 1: The cross-section of the radial nerve (RN) just above the humerus and between the Brachialis muscle (BB) and the lateral head of the triceps (LT) on musculoskeletal ultrasound

taken as an internal control while comparing with the pathological side in the upper limb.^[12] The ultrasonographic measurement of the CSA of the RN along with q-DASH score and NPRS score was assessed at zero, 4, and 12 weeks.

The sample size was calculated based on a systematic review^[13] that compared the effectiveness of corticosteroid injections with conservative management in LE. The study observed that large effect sizes (ES) favoured corticosteroid injections at the short-term follow-up. To detect large-scale ES (0.8), the minimum required sample size with 90% power of the study and two-sided alpha errors of 5% were 33 patients per group and, therefore, the sample size was taken as 70 (35 per group).

Randomization was done via a computer-based randomization system. Blocks of size four were created; for every four patients randomized, two received corticosteroid injections and the other two received conservative treatment. Blocks were generated according to the generated number. The envelope method was used to conceal group allocation.

Blinding was not done in this study; however, the statistical analysis investigator was unaware of group allocation. The person who did the primary and final assessment was different from the person who did the intervention.

The person who took the initial ultrasonographic measurements also took the measures during the follow-up visits to avoid inter-observer variations.

Statistical analysis

The data were entered in MS Excel spreadsheet, and analysis was done using Statistical Package for Social Sciences version 21.0. Categorical variables were presented in number and percentage (%), and continuous variables were presented as mean \pm SD and median. The Kolmogorov–Smirnov test

tested the normality of data. If the normality was rejected, a non-parametric test was used. Missing values were filled using imputed missing data values by taking age and baseline values as independent variables. Quantitative variables were compared using the independent *t*-test/Mann–Whitney test (when the data sets were not normally distributed) between the two groups, and the Friedman test for repeated measures is used to see the differences within the same arm. Qualitative variables were correlated using the Chi-square test/Fisher’s exact test. Spearman rank correlation coefficient was used to assess the association of various parameters with each other. A *P* value of < 0.05 was considered statistically significant.

Results

A total of 110 patients were assessed for eligibility. Forty patients were excluded, and the remaining 70 patients were randomized to Groups A and B in a 1:1 ratio. None of the two groups had a loss to follow-up at the 4-week follow-up. Group A had two patients lost to follow-up at 12 weeks, and Group B had one patient who was lost to follow-up at 12 weeks. The flow diagram for the study participants is depicted in Figure 3. The mean age of the total (n=70) participants was 44.40 ± 7.25 years. Most of the patients were female (68.57%), and most were right-handed (97.14%). A few patients developed LE on the non-dominant side; however, the majority (86.74%) developed it on the dominant side. The mean duration of symptoms in these patients was 10.96 ± 9.30 weeks ranging from 7 to 52 weeks. The mean intensity of pain on the NPRS score was 4.74 ± 0.81, and the mean disability score was 37.53 ± 10.16 on the q-DASH scale ranging from 13.6 to 59.1. Patients were randomized into Groups A and B. The baseline characteristics were comparable, as shown in Table 1.

There was a statistically significant reduction in pain intensity as measured by NPRS and improved health-related quality of life as measured by q-DASH within both the groups at the 12-week follow-up compared to baseline. There was a statistically significant improvement at the 4-week follow-up favouring Group B compared to Group A. There was no statistically significant difference between Groups A and B at the 12-week follow-up concerning NPRS and q-DASH, as shown in Table 2.

The RN’s CSA at the unaffected side was measured at baseline, and the same value was carried forward at the 4- and 12-week follow-ups, whereas the measurement on the affected side was taken at baseline and 4- and 12-week follow-ups.

In both Groups A and B, the difference in the CSA of the RN was not statistically significant at either the SG or at the AF between the affected side and the unaffected side at baseline; the difference of CSA on the affected side remained statistically insignificant at the 4- and 12-week follow-up at both the SG or at the AF [Table 3].

In Group A, the CSA of the RN of the affected side at the SG and at the AF was not statistically significant at any of the

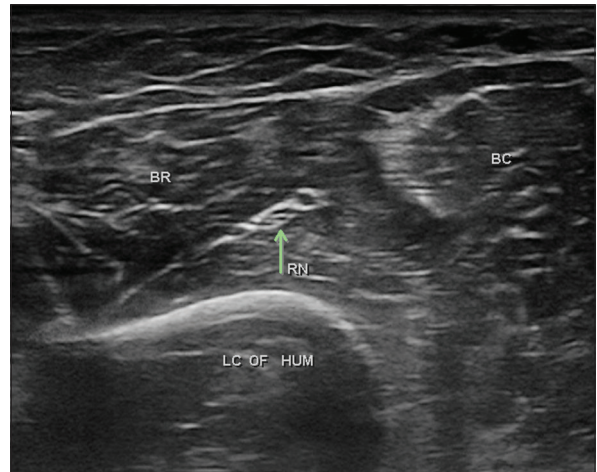


Figure 2: The radial nerve at the humerus antecubital fossa just before branching into the superficial radial and deep branch. Footnote to Figure 2: The cross-section of the radial nerve (RN), seen in the intermuscular septum, between the brachioradialis (BR) and brachialis (BC) muscles, 3–4 cm above the lateral condyle of the humerus (LC OF HUM)

Table 1: Baseline characteristics of participants

	Group A (n=35)	Group B (n=35)	P
Age (years)	43.4±7.59	45.4±6.87	0.25
Sex (male:female)	9:26	13:22	0.31
Hand dominance (left:right)	1:34	1:34	1.0
Duration (weeks)	9.5 (6, 12)	7 (6, 16)	0.65
NPRS	5 (4, 5)	5.5 (4, 5)	0.68
q-DASH	38.6 (29.5, 50)	36.4 (29.5, 43.2)	0.35

NPRS=Numeric pain rating scale, q-DASH=the Quick Disabilities of the Arm, Shoulder, and Hand questionnaire. The characteristics such as age, sex, hand dominance, duration of symptoms, pain and disability score were comparable at baseline in Groups A and B. Data for age, sex and hand dominance expressed as mean±standard deviation or ratio while duration, NPRS, q-DASH depicted as median (first quartile, third quartile)

follow-ups compared to baseline. In Group B, the CSA of the RN of the affected side at the SG was not statistically significant at any of the follow-ups compared to baseline. However, in group B, reduction in CSA of the RN was statistically significant at the AF at the 12-week follow-up on the affected side compared to the baseline.

The RN’s CSA at the SG and the AF on the affected sides were subsequently compared between Groups A and B to see if a differential response on RN’s CSA exists with the two treatment approaches.

There was no statistically significant difference in CSA at either the SG or at the AF at baseline, 4 weeks, and at the 12-week follow-up on comparing the affected sides of Groups A and B [Table 4].

There was a moderate positive correlation between the RN’s thickness at the SG and the score on the q-DASH scale in Group A at the 12-week follow-up. There was a moderate positive correlation between the RN’s thickness at the AF and the score on the q-DASH scale in Group A at the 4-week follow-up.

Table 2: Comparison of pain intensity score (NPRS) and disability score (q-DASH) within and between Groups A and B

Variables	Time-point	Group A (n=35)	Group B (n=35)	P (between groups)
NPRS	Baseline	5 (4,5)	5.5 (4, 5)	0.68
	4 weeks	2.5 (2, 3)	3.5 (2, 4)	0.022*
	12 weeks	3 (1, 3)	2 (1, 3)	0.34
	P (within the groups)	0.001*	0.001*	
q-DASH	Baseline	38.6 (29.5, 50)	36.4 (29.5, 43.2)	0.35
	4 weeks	30.7 (15.9, 34.4)	25.5 (20.5, 31.8)	0.33
	12 weeks	27.3 (11.4, 34.1)	15.9 (11.4, 22.7)	0.22
	P	0.01*	0.01*	

Data have been depicted as median (first quartile, third quartile). NPRS=Numeric pain rating scale, q-DASH=the Quick Disabilities of the Arm, Shoulder, and Hand questionnaire. The table shows the effect of the two treatment approaches on NPRS and q-DASH at baseline, 4 weeks, and 12 weeks' follow-up. *Depicts significance at the level of 0.05

Table 3: Comparison of the radial nerve thickness (mm²) of affected versus unaffected side at antecubital fossa and spiral groove

Variables	Time point	Group A (n=35)			Group B (n=35)		
		Affected side	Unaffected side	P	Affected side	Unaffected side	P
At cubital fossa	Baseline	1.72±0.75	1.40±0.49	0.12	1.92±0.74	1.60±0.55	0.12
	4 weeks	1.66±0.64	1.40±0.49	0.14	1.92±0.74	1.60±0.55	0.12
	12 weeks	1.52±0.51	1.40±0.49	0.42	1.52±0.71	1.60±0.55	0.38
At spiral groove	Baseline	4.37±1.22	3.77±0.84	0.062	4.37±1.19	3.83±0.86	0.094
	4 weeks	4.29±1.07	3.77±0.84	0.084	4.34±1.14	3.83±0.86	0.095
	12 weeks	4.23±1.12	3.77±0.84	0.15	4.03±1.29	3.83±0.86	0.74

The difference in radial nerve thickness (mm²) on the affected side compared to the unaffected side at baseline, 4 weeks, and at 12 weeks' follow-up. Data have been depicted as mean±standard deviation. Mann-Whitney U test is used to compare the values between the two arms. *Depicts significance at the level of 0.05

Table 4: Comparison of the radial nerve thickness (mm²) of the affected side at the antecubital fossa and the spiral groove within and between Groups A and B

Radial nerve thickness	Time point	Group A (n=35)		Group B (n=35)		P (between groups)
		Affected side	Affected side	Affected side	Affected side	
At cubital fossa	Baseline	1.72±0.75	1.92±0.74	0.99		
	4 weeks	1.66±0.64	1.92±0.74	0.19		
	12 weeks	1.52±0.51	1.52±0.71	0.69		
	P (within the groups)	0.514	0.015*			
At spiral groove	Baseline	4.37±1.22	4.37±1.19	0.87		
	4 weeks	4.28±1.07	4.34±1.14	0.76		
	12 weeks	4.23±1.12	4.03±1.29	0.47		
	P (within the groups)	0.665	0.058			

The effect of the two treatment approaches on radial nerve thickness at baseline, 4 weeks, and 12 weeks' follow-up. Data have been depicted as mean±standard deviation. The Friedman test for repeated measures is used to see the differences within the same arm, and the Mann-Whitney U test is used to compare the values between the two arms. *Depicts significance at the level of 0.05

Table 5: Analysis of correlation between radial nerve thickness and dysfunction

Parameter	Time point	Group A		Group B	
		Spearman's rho (p)	P	Spearman's rho (p)	P
At spiral groove	Baseline	0.14	0.43	0.14	0.42
	4 weeks	0.32	0.06	0.29	0.08
	12 weeks	0.42	0.02*	0.31	0.07
At antecubital fossa	Baseline	0.25	0.15	0.24	0.16
	4 weeks	0.41	0.02*	0.34	0.05
	12 weeks	0.24	0.16	0.46	0.005*

Spearman's correlation analysis between the radial nerve thickness (mm²) on the affected side and the score on the q-DASH scale. *Correlation is significant at the 0.05 level (two-tailed)

There was a moderate positive correlation between the RN's thickness at the AF and the score on the q-DASH scale in Group B at the 12-week follow-up, as shown in Table 5.

Discussion

A local corticosteroid injection as an add-on to conservative treatment proved to be more efficacious than conservative treatment at the 4-week follow-up concerning its effect on pain intensity. However, this was not the case at the 12-week follow-up, where both fared relatively similarly. Quality of life improved with both types of approaches; however, no one method was superior to the other. Our study's findings corroborate with a recent study^[14] wherein placebo injection with the physiotherapy group showed a gradual and very similar improvement pattern. In contrast, the corticosteroid injection with the physiotherapy group showed a marked improvement at 6 weeks, but then a lower success rate at 12 and 26 weeks.

The CSA was not found to be more on the affected side than the unaffected side, signalling that sensitization, even

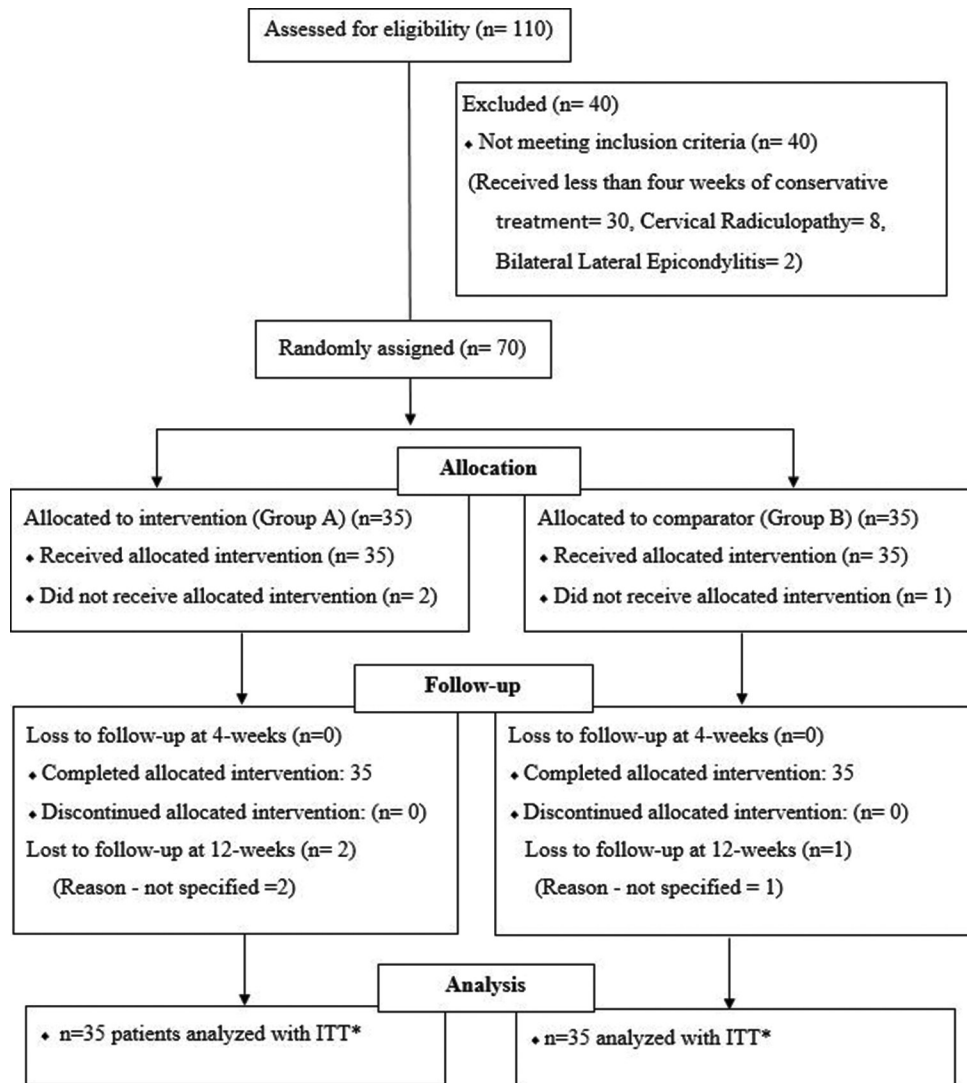


Figure 3: Study flow diagram

if present, did not show up as increased thickness of the RN on the involved sides. This finding was found in both Groups A and B. This finding does not support the theoretical framework presuming that the RN's thickness is a marker of sensitization.

There was no differential response to the RN's thickness with the two approaches suggesting that the RN's involvement concerning its CSA does not have a role despite it being the afferent supply from the common extensor tendon.

The patient's disability did not correspond to the nerve thickness except on a few occasions where a moderate correlation was found.

This study's strength is that it gives insight into the theoretical framework in the backdrop of increasing awareness of the sensory system's work contributing to musculoskeletal pain, like tendinopathy.^[15,16] Nervous system sensitization, both peripherally and centrally, can be defensive and beneficial in the short term in

response to nociceptive feedback or inflammation. In situations where the tendon torment has persevered, this sharpening of the sensory system might be maladaptive, and this way adds to tireless agony and conceivable disability.^[17,18]

The major limitation of this study is that the assumption that CSA of the RN is a surrogate marker of sensitization may be flawed and remains a matter of speculation based on current literature. The study's novelty lies in the fact that it may spur further research investigating the process of sensitization in persistent tendinopathies.

Conclusions

The conservative treatment along with a local steroid injection is more efficacious in the short term; however, this superiority is lost at the longer follow-up concerning both pain intensity and disability. The RNs thickness does not change significantly with time as the patient's symptoms improve. This refutes its role to some extent in the pathogenesis of LE.

Key Points

1. Management with steroid injection may be considered when the situation demands a fast response.
2. The CSA of the RN as a surrogate marker of sensitization is flawed and we should be on the lookout for other attributes.
3. More research on RN's putative role using other methods is needed.

Ethical guidelines

The study was approved by the Institute Ethics Committee, All India Institute of Medical Sciences, New Delhi, India (approval no. IEC/PG/322/6/2017), before commencing the work. Written informed consent was taken prior to the study. All personal details of the participant were kept confidential throughout the course of the study.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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