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ULTRASOUND GUIDED AUTOLOGOUS BLOOD INJECTION VERSUS ULTRASOUND THERAPY IN THE MANAGEMENT OF CHRONIC LATERAL EPICONDYLITIS: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

INTRODUCTION: Tendinopathy is common in professional athletes as well as in sedentary people. It occurs 30% -50% of all sports related injuries. Injection of autologous blood has been reported beneficial for the treatment of tendinopathy. It is hypothesized that transforming growth factor-β and basic fibroblast growth factor carried in the blood will act as humoral mediators to induce the healing cascade. Musculoskeletal ultrasound can document the pathology prior to the injection and accurately identify the site for injection. It also helps in monitoring tendon healing.

MATERIALS AND METHODS: This randomized controlled trial was carried out after obtaining permission from Research Ethics Board between September 2016 to August 2018 in the Department of Physical Medicine and Rehabilitation (PMR), Regional Institute of Medical Sciences (RIMS), Imphal, Manipur. 40 patients with lateral epicondylitis were included in this study. The independent variable considered were age, sex, occupation, duration and side of affection. The intervention group received autologous blood injection (ABI) whereas the control group received a 5-minute ultrasound application, once a day for 10 days at a frequency of 1 MHz and average intensity of 0.1 W/cm^2.

RESULTS AND OBSERVATIONS: Out of 40 patients recruited, 25 patients were female (62.5%) and 15 were males (37.5%). The intervention group (ABI group) consisted of 12 females and 8 males with a mean age group of 46.55±9.64 years while the control group (Ultrasound group) consisted of 13 females and 7 males with a mean age group of 49.65±8.18 years. There was significant improvement in VAS and PRTEE score in autologous blood injection group compared to Ultrasound group in 6 months follow up. There were also significant improvement in neovascular, echotexture grading and tendon size in ABI group compared to the Ultrasound group in 6 months follow-up.

CONCLUSION: The study showed that single injection of ultrasound guided autologous blood injection is significantly more effective in reducing pain and disability in resistant lateral epicondylitis at 6 months as compared to Ultrasound therapy. This study also confirmed that there was significant improvement of ultrasound parameters in autologous blood injection group compared to Ultrasound group and may be considered as an alternative to surgery in resistant lateral epicondylits.

KEYWORDS : Tendinopathy, Lateral epicondylitis, Autologous blood injection (ABI), Patient Rated Tennis Elbow Evaluation (PRTEE) , Musculoskeletal ultrasonography, Ultrasound therapy.

INTRODUCTION

Tendon pain is common in professional athletes as well as in sedentary people. It occurs 30% -50% of all sports related injuries.[1]Tendinopathy (often called tendonitis or tendinosis) is the most common tendon disorder. It is characterized by activity related pain, focal tenderness and decreased range of movement in the affected area. Tendinopathy can occur in any tendon. Tendinopathy is not characterized by an inflammatory response but rather infiltration of fibroblasts and vessels ensuing chronic cycle of tendon degeneration and repair resulting in a weakened tendon.[2]Lateral epicondylitis also known as the tennis elbow is a term used to describe myriad of symptoms around the lateral aspect of the elbow which occurs more frequently in nonathletes than athletes.[3] The disorder arises as a result of repetitive movements of the involved muscles particularly in the working age group. The disease imparts significant disability in terms of the quantity and quality of work done. Tennis elbow may also cause significant weakness of grip strength particularly with the elbow in extension.[4]Incidence of injury has been reported in various forms. For instance, in club gymnastics injury rates vary between 2 to 4 and 39.9 per 100 school children per year.[5] The peak incidence is in the early fifth decade and a nearly equal gender incidence is seen.[6]The pathology of lateral epicondylitis results from overuse of the extensor muscles leading to degenerative pathology of the involved tendons.[7] Although it is known as a tendonitis, histopathologic studies have shown that it is associated with few inflammatory cells but more associated with hypertrophy of fibroblasts, abundant disorganized collagen, hyperplasia of vascular elements, apoptosis and extracellular matrix breakdown.[8]

The diagnosis of tennis elbow is usually made clinically by localizing discomfort at the origin of the extensor carpi radialis brevis. Tenderness is present over the lateral epicondyle approximately 5 mm distal and anterior to the midpoint of the lateral epicondyle. Pain usually is exacerbated by dorsiflexion of wrist against resistance and forearm supination and on grasping objects.[3]Resistant lateral epicondylitis will be diagnosed if there is persistent pain and tenderness on or near lateral epicondyle despite all conservative treatments spanning for a minimum period of 6 months along with 2 of 3 pain provocative tests- gripping, Cozen's test and Mill's manoeuvre.[9] Numerous different methods have been proposed to treat tendinopathy, such as eccentric training, the injection of corticosteroids and sclerosants, prolotherapy, extracorporeal shockwave therapy and glyceryl trinitrate patches[10]. Corticosteroid injection has been shown to provide short term relief but relapse rates are high. Recent literature suggests that corticosteroid injections may actually have deleterious effects after their short-term pain relief.[11]Currently, eccentric training is the first choice of treatment of most practitioners, although the methodological quality of the studies suggesting efficacy has recently been questioned.[12,13]

Autologous blood injection has emerged as the one of the acceptable modalities of treatment. Long term studies over a larger group of patients are however lacking. Being cheap, available and easy method of treatment, it should be considered as a treatment modality before opting for the surgery.[14]Musculoskeletal Ultrasound can document the pathology prior to the injection and accurately identify the site for injection and there after monitor tendon healing .[15]Tendons throughout the body, including those implicated in lateral

epicondylosis such as the extensor carpi radialis brevis heal more slowly than most other types of tissues partly due to the lower vascular supply.[16, 17] It is hypothesized that autologous blood preparations may help with healing by initiating an inflammatory process while also delivering nutrients and high concentrations of growth factors that may promote tendon healing.[18]Diagnostic ultrasound has its dependence on body habitus. Although recent advances have improved high frequency linear array transducers, a lower frequency curvilinear transducer (3–5 MHz) may be needed to provide adequate penetration for deeper structures. With greater depth of penetrance though resolution can be sacrificed making musculoskeletal ultrasonography limited as a modality in obese or muscular patients. However, recent advances in tissue harmonics have improved visualization and resolution of deeper structures even in these challenging cases.[19]

Low-intensity ultrasound therapy (LIUS) has been shown to be beneficial in accelerating fracture healing and has produced positive results in animal tendon repair.[20]

This study was conducted to find out the efficacy of musculoskeletal ultrasonography guided autologous blood injection in chronic lateral epicondylitis and assess the tendon healing by musculoskeletal ultrasonography after autologous blood injection.

AIMS AND OBJECTS

1. To study the efficacy of ultrasound guided autologous blood injection in chronic lateral epicondylitis.
2. To assess the tendon healing by musculoskeletal ultrasonography after autologous blood injection.

MATERIAL AND METHODS

This randomized controlled trial was carried out after obtaining permission from Research Ethics Board between September 2016 to August 2018 in the Department of Physical Medicine and Rehabilitation (PMR), Regional Institute of Medical Sciences (RIMS), Imphal, Manipur. A total of 40 patients with lateral epicondylitis were included in this study using block of four randomization technique.

Inclusion criteria:

- Tendinopathy more than 6 months
- Ultrasound features of tendinopathy
- Normal hemoglobin value
- Pain severity with minimum score of ≥5 based on 10 scale VAS (Visual Analogue Scale)
- Willingness to comply with the treatment and follow-up assessments

Exclusion criteria:

- Platelet value $<150000/mm^3$
- Bleeding disorders
- History of steroid injection in last 6 weeks
- History of any malignancy
- Systemic illnesses including ischemic heart disease, diabetes, rheumatoid arthritis, hepatitis
- Any fracture, bony malformation, articular lesions at elbow

Procedure

Patient's baseline complete haemogram and musculoskeletal ultrasonography of the affected elbow was taken before the intervention.

In group A, 2 ml of venous blood was drawn from the contralateral upper limb and blood was injected after anesthetizing the area with local injection of 2 ml of 1% lignocaine solution. The injection was administered in the operation theatre taking aseptic precautions. Patient was seated or supine with arm is on the table with wrist in prone and lateral compartment is facing forward. Transducer was placed long axis to the common extensor tendon at the lateral epicondyle .The needle was introduced under ultrasound guidance just proximal to the lateral epicondyle and the venous blood was injected on the undersurface of the extensor carpi radialis brevis muscle.

In group B, The subjects in the ultrasound group received a 5-minute ultrasound application, once a day for 7 days at a frequency of 1 MHz and average intensity of $0.1\ W/cm^2$.

All subjects were advised to rest and moderate their activities for 2 weeks to avoid aggravation of their symptoms. Paracetamol was given as rescue drug.

Outcome variables were measured at baseline before intervention and follow up assessment was done at 2 weeks, 3 months and 6 months. But Ultrasonography examination was carried out at baseline, 3 months and 6 months follow-up.

The outcome measures considered in this study were

1. Visual Analogue Scale (VAS)
2. Patient Rated Tennis Elbow Evaluation (PRTEE)
3. Ultrasnographic assessments

1. **Visual Analogue Scale (VAS)** [21] for pain is a 100 cm horizontal line on which the patient's pain intensity is represented by a point between the extremes of "no pain at all" and "worst pain imaginable". The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in centimeters from the left hand end of the line to the point that the patient marks.
2. **Patient Rated Tennis Elbow Evaluation (PRTEE)[22] :-** The PRTEE, formerly known as the Patient-Rated Forearm Evaluation Questionnaire (PRFEQ), is a 15-item questionnaire designed to measure forearm pain and disability in patients with lateral epicondylitis. It consists of two subscales (pain and function). The sensitivity and specificity values associated with the PRTEE were 0.94 (95% CI=0.83–0.98) and 0.78 (95% CI=0.58–0.91) respectively.[21]
3. **Sonographic assessment**[23]

I. Echotexture grading scale

0 Normal
1a Hypoechogenicity less than one third of the tendon
1b Hypoechogenicity in between one third to two third of the tendon
1c Hypoechogenicity in more than two third of the tendon
2 Partial thickness tear
3 Full thickness tear

II.Neovascularization grading scale-

0 No neovascularization
1 Neovessels on the tendon surface
2 1 or 2 intratendinous neovessels
3 3 or more intratendinous neovessels

III.Tendon size- In mm.

IV.Calcification-

Statistical analysis

Data was collected in a pre-tested proforma. Analysis was done using Statistical Package for the Social Sciences, SPSS 21 version. For descriptive statistics, mean and standard deviation was used. For continuous variable Student's t-test was used. Chi-square and Fisher' exact test were used for categorical variable. P-value < 0.05 was taken as statistically significant.

RESULTS

Table 1 shows the baseline characteristics of the study

participants. 25 patients were females which constituted 62.5% of total patients and 15 were males constituting 37.5% of total sample size. The intervention group (ABI group) consisted of 12 females and 8 males with a mean age group of 46.55±9.64 years while the control group (Ultrasound group) consisted of 13 females and 7 males with a mean age group of 49.65±8.18 years. The baseline characteristics of both the groups were shown in Table1 and showed no statistically significant difference in both the groups. As far the side of involvement is concerned, majority of patients in both the groups had right sided involvement. The mean duration of symptoms in ABI group was 8.87±2.37 months and where as in the Ultrasound group it was 8.91±2.95 months.

Table 2 shows the mean improvement of VAS score which was found to be statistically significant ($p<0.05$) in both the ABI and Ultrasound groups. At 2 weeks and 3 months follow-up, both the group showed significant improvement. But at 6 months follow-up, ABI group showed more improvement of VAS score compared to the Ultrasound group and which was statistically significant ($p<0.000$).

Table 3 shows the mean improvement of PRTEE score which was found to be statistically significant in both the ABI and Ultrasound group at 2 weeks and 6 months follow-up. But ABI group showed more improvement of PRTEE score compared to the steroid group at 6 months follow-up ($p<0.000$).

Table 4 shows echotexture improvement in both the group having normal echotexture pattern that is grade 0 at the end of three months follow-up however the group receiving ABI showed more improvement compared to the group receiving ABI in terms of echotexture grading improvement ($p<0.001$). But at the end of 6 month improvement in term of normal echotexture grading pattern was more significant in the group receiving ABI as compared to the group receiving Ultrasound ($p=0.000$).

Table 5 shows that there were improvement in term of neovascularization in both the group at 3 month and 6 month follow-up but at the end of 6 month ABI group showed more improvement compared with the group receiving Ultrasound with no statistical significance ($p>0.05$)

Table 6 shows that the mean reduction in tendon size were found to be statistically significant ($p<0.05$) in both the ABI and steroid group. But ABI group showed more improvement at 6 month compared to the steroid group.

DISCUSSION

Tennis elbow is a common tendinopathy that can be quite resistant to treatment and often affect the daily activities of the people. Many conservative treatment strategies have been used in treatment of lateral epicondylitis as first line but the treatment response is often inadequate. Conservative management like activity restrictions, orthotics and splints, NSAIDs, physical modalities has been tried. A recent Cochrane review concluded that steroid injection has only short term effect and has poor outcome in long term.[24] Surgical treatment remains a last option and many a times it involves considerable cost, morbidity and complications. Most of the people refuse to opt for surgical treatment because of fear and ignorance. Thus there is an evident need for effective alternative conservative therapies. Growth factors have shown promising results in field of tendon injury and repair. These are usually given in form of whole blood, platelet rich plasma or bone marrow aspirate injection. According to recent report by Jindal et al, autologous blood injection showed marked improvement in patients with chronic refractory lateral epicondylitis.[25]

With this background, the present study was conducted in 40 patients with resistant lateral epicondylitis. The total sample was randomized and allocated to two groups: ABI group who received single injection of autologous blood and Ultrasound group.

The present study reveals that mean age of the study population group were 46.55±9.64 years in ABI group and 49.65±8.18 years in steroid group. In a study conducted by Jindal et al[24], the mean age of study group were 37.32±7.52 years in ABI group and 39.04±6.67 years in steroid group. Lateral epicondylitis is most commonly seen in working population because this condition is basically an overuse syndrome.

In present study, housewives constituted 52.5% and manual labourers constituted 35% of total patients. In a study conducted by Gani N et al[14], 71 % of total females were housewives and 77% of total males were manual labourers. This could be explained by the repeated microtrauma to extensor carpi radialis brevis due to overuse of this muscle in activities involving repetitive manual works.

The mean duration of symptoms in ABI group was 8.87±2.37 months where as in steroid group it was 8.91±2.95 months. Bostan B et al[26] also found in their study that mean duration of the symptoms was 8.4 months. The subjects selected for this study were resistant cases who had already been tried with conservative management and have not improved symptoms for at least six months.

The ABI group consisted of 12 females and 8 males whereas Ultrasound group consisted of 13 females and 7 males. It was found that females were more commonly affected than males as in previous studies. This higher incidence in females may be explained by the type of household activities where repeated supination and pronation is required.

Majority of patients in both the groups had right sided involvement which was their dominant side. In the study conducted by Jindal et al [25], who also compared autologous blood injection and Ultrasound injection in patient suffering from chronic lateral epicondylitis, they found similar findings about the laterality of this condition. Majority of their patients had right sided dominant hand involvement. These findings explain the theory of overuse injury as the pathogenesis of lateral epicondylitis.

In the present study , there was significant improvement in the mean of VAS score in both the groups at 2 weeks, 3 months and 6 months follow up ($p<0.05$).

In ABI group, the mean VAS score improved from 6.15±0.72 to 4.40±0.94 at 2 weeks and further improved to 2.60±0.94 and 1.5±0.51 at 3 months and 6 months follow up respectively($p<0.05$). In a study conducted by Monreal R et al[27], they found similar improvement of VAS score at an average 2.5 weeks (range 1 week to 8 weeks). In their study, follow up was done at 2, 4, 6, 10 and 12 weeks and improvement in pain was evident as early as at the end of 2 weeks.

There was improvement of PRTEE scores in both ABI and steroid injection groups at 2 weeks and 6 months follow-up. The ABI group baseline PRTEE was 55.35±12.07 which reduced to 40.55±9.99 and 13.75±3.14 at 2 week and 6 month follow-up. But in the group receiving Ultrasound, the baseline PRTEE was 59.85±5.78 which reduced to 49.70±5.52 and 35.20±6.54 respectively. So improvement was more in ABI group compared to the steroid group at 6 month follow-up. In a study conducted by Arik HO et al [28], they found the similar improvement of PRTEE scores at 2 weeks and 6 months follow-up. But ABI group showed more significant improvement of PRTEE scores compared to the steroid group at 6 month follow-

up ($p<0.05$).

There was significant improvement of echo-texture grading in ABI group compared to Ultrasound group in 3 months and 6 months follow up. In a study conducted by Suresh SPS et al[29], they found that hypo-echoic change score decreased from 6.45 points at baseline to 3.85 points at 10 months follow-up and this decrease was found to be statistically significant ($p=0.001$). Neo-vascularity decreased between pre-procedure when there was a mean score of 6.10 points and post procedure at 10 months when there was a mean of 3.60 points and this decrease was found to be statistically significant ($p=0.001$). In this study we could not find any significant improvement in terms of neo-vascularity. This probably would suggest requiring a long term follow-up to see the effects of intervention in term of nevascular changes.

There was significant reduction of tendon size in both the groups but size reduction is more in ABI group compare to group receiving steroid injection at 6 months follow-up. In ABI group baseline tendon size was 4.62 ± 9.32 mm which reduced to 4.04 ± 10.07 mm and 3.46 ± 7.98 mm at 3 months and 6 months follow-up respectively. On the other hand Ultrasound group baseline tendon size was 4.50 ± 5.78 mm which reduced to 4.16 ± 5.16 mm and 3.73 ± 4.11 mm at 3 month and 6 month follow-up respectively. In a study conducted by Gautam VK et al [30], they found similar kind of reduction in tendon size in ABI group .

Patients who received the ABI and steroid injection did not have any serious adverse effects during or after procedure. There was mild swelling and pain at the injection site on the day of injection in 5 patients of AB group. The pain was managed with Paracetamol tablets as and when required, but they were advised not to use heat or anti-inflammatory drugs post injection.

Additionally, there is no consensus about frequency, number of autologous blood injection and volume of autologous blood to be injected in chronic resistant lateral epicondylitis. However the present study showed significant pain and function improvement with a single autologous blood injection. Hence the results of this study may provide insights into effect of autologous blood in chronic tendinopathies. It may also contribute to identify as one approach for autologous blood injection in resistant tennis elbow.

Long term follow up may require for studying the long term effect of autologous blood over Ultrasound group.

CONCLUSION

The present study was done to find out the efficacy of ultrasound guided autologous blood injection in chronic lateral epicondylitis to improve pain and function. The study showed that single injection of ultrasound guided autologous blood injection is significantly more effective in reducing pain and disability in resistant lateral epicondylitis at 6 months as compared to Ultrasound group. This study also confirmed that there is significant improvement of ultrasound parameters in autologous blood injection group compare to Ultrasound group and may be considered as a novel alternative for surgery in resistant cases.

ANNEXURE 1

Table 1.Baseline characteristics of study groups

Characteristics		Autologous blood group (n=20) (Mean±SD) (N)	Ultrasound group (n=20) (Mean±SD) (N)
Mean age (year)		46.55±9.64	49.65±8.18
Sex	Male	8	7
	Female	12	13
Side of affection	Right	14	13
	Left	6	7
Duration(months)		8.87±2.37	8.91±2.95
Occupation	Manual laborers	6	8
	Government employees	3	2
	House wife	11	10
Religion	Hindu	15	17
	Muslim	3	1
	Christian	2	2
Domicile	Rural	11	9
	Urban	9	11
Qualification	Illiterate	4	2
	Primary	19	4
	secondary	4	4
	Higher secondary	7	10
Mean VAS		6.15±0.74	6.30±0.86
Mean PRTEE		55.35±12.07	59.85±5.78

Table 2: Between and within group comparison of VAS pain at different time points

VAS score	Study groups		P value (Between group)
	Autologous blood	Ultrasound	
Baseline	6.15±0.74	6.30±0.86	0.560
2 weeks	4.40±0.94	3.50±0.51	<0.001
3 months	2.60±0.94	3.20±0.41	<0.013
6 months	1.5±0.51	4.3±0.48	<0.000
P value (within group)	0.000	0.000	

Table3: Between and within group compression of PRTEE scores at different time points

PRTEE score	Study groups		P value (Between group)
	Autologous blood	Ultrasound	
Baseline	55.35±12.07	59.85±5.78	0.140
2 weeks	40.55±9.99	49.70±5.52	0.001
3 months	25.65±8.13	37.90±3.94	0.000
6 months	13.75±3.14	35.20±6.54	<0.000
P value(within group)	0.000	0.000	

Table 4: Echotexture grading Comparison in two groups of patients studied at different time points

Echotexture grading	Study groups		Total (n=20)	P value
	Autologous blood (n=20)	Ultrasound (n=20)		
1 baseline				0.142
• Grade 0	0(0%)	0(0%)	0(0%)	
• Grade 1a	6(30%)	11(55%)	17(42.5%)	
• Grade 1b	12(60%)	9(45%)	21(52.5%)	
• Grade 1c	2(10%)	0(0%)	2(5%)	
3 months				0.676
• Grade 0	2(10%)	1(5%)	3(7.5%)	
• Grade 1a	16(80%)	18(90%)	34(85%)	
• Grade 1b	2(10%)	1(5%)	3(7.5%)	
• Grade 1c	0(0%)	0(0%)	0(0%)	
6 months				0.001
• Grade 0	17(85%)	6(30%)	23(57.5%)	
• Grade 1a	3(15%)	14(70%)	17(42.5%)	
• Grade 1b	0(0%)	0(0%)	0(%)	
• Grade 1c	0(0%)	0(0%)	0(0%)	

Table 5: Neovascularization grading -Comparison in two groups of patients studied at different time points

Neo Vascularization grading	Study group		Total (n=40)	P value
	Autologous blood (n=20)	Ultrasound (n=20)		
1 baseline				1.000
• Grade 0	4(20%)	4(20%)	8(20%)	
• Grade 1	10(50%)	9(45%)	19(47.5%)	
• Grade 2	6(30%)	7(35%)	13(32.5%)	
3 months				0.145
• Grade 0	8(45.65%)	12(54.35%)	20(50%)	
• Grade 1	9(45.65%)	4(41.30%)	13(32.5%)	
• Grade 2	3(8.70%)	4(4.35%)	7(17.5%)	
6 months				1.000
• Grade 0	17(85)	14(70%)	31(77.5%)	
• Grade 1	3(15%)	6(30%)	9(22.5%)	
• Grade 2	0(0%)	0(0%)	0(0%)	

Table 6: Tendon size Comparison in two groups of patients studied at different time points

Tendon Size (in mm)	Study groups		P value (Between group)
	Autologous blood	Ultrasound	
Baseline	4.62±9.32	4.50±5.78	0.187
3 months	4.04±10.07	4.16±5.16	0.078
6 months	3.46±7.98	3.73±4.11	0.015
P value (Within group)	0.000	0.000	

ANNEXURE 2

Figures

Figure 1: Ultrasound image showing needle position

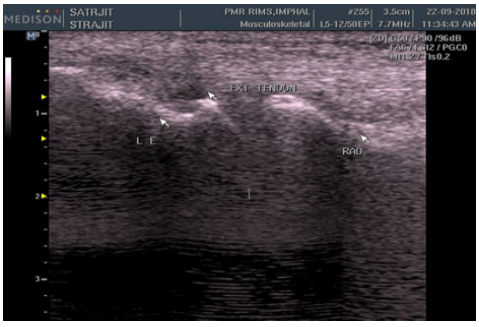

Figure 2: Ultrasound image of lateral epicondyle

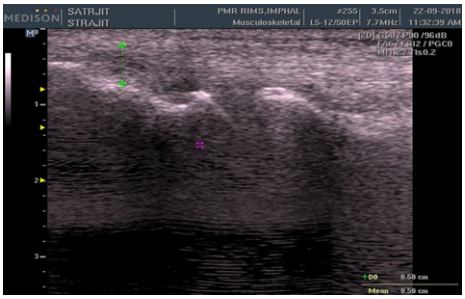

Figure 3: Measurement of tendon thickness

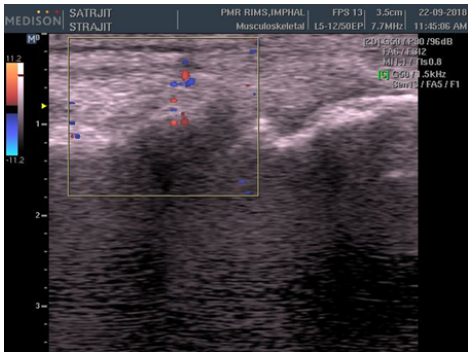

Figure 4: Ultrasound image showing neovascularization

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