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RESEARCH ARTICLE

COMPARISON OF ULTRASOUND GUIDED PLATELET RICH PLASMA INJECTION AND EXTRACORPOREAL SHOCKWAVE THERAPY FOR TREATMENT OF HAGLUND'S SYNDROME: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Pain in the posterior aspect of heel with a deformity is a fairly common condition. It affects 1 in 8 persons over age fifty.[1] Pain can be due to Haglund syndrome, retrocalcaneal bursitis, plantar fasciitis, achilles tendinosis,avulsion of Achilles tendon, seronegative spondyloarthropat hies. Haglund syndrome is a very common clinical condition where patient presents clinically with pain at the posterior heel, which may be associated with limping and swelling, pain is prominent while the patient begins to walk after rest. First described by Patrick Haglund in 1927. It is the abnormality of the posterosuperior part of the calcaneus, where there is bony enlargement near the attachment of the Achilles tendon that leads to myriads of combination of pathology, adjoining soft tissues can get irritated when this bony lump rubs against rigid shoes leading to retrocalcaneal bursitis, achilles tendon bursitis, and thickening and inflammation of the achilles tendon. The bony enlargement is called Haglund's deformity, which is also known as retrocalcaneal exostosis, Mulholland deformity, and 'pump bump'. Common among middle aged females and are often bilateral. Mostly an idiopathic condition, contributory factors like tight Achilles tendon, a high arch of the foot, over-practice in runners, tight or poorly fitting shoes, or altered biomechanics of foot joints can play a role in etiopathogenesis of the disease.

Introduction:-

Clinical evaluation and lateral radiographs of the ankle are mostly enough to make a diagnosis of Haglund's syndrome, X-ray ankle in lateral projection, may show bony enlargement at the attachment of the Achilles tendon, any intratendinous calcifications, modification in Kager's triangle - typical of retrocalcaneal bursitis. Treatment include reassessment of the shoe of the patient and heel pads or heel lifts in the cases of high arched feet. The aim is to reduce pain therefore, an ice therapy to deal with swelling, reduction of physical activity and rest. Stretching

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exercises of the gastrocnemius-soleus complex. Oral or topical anti-inflammatory drug therapy can be added. Physical therapy like ultrasound, laser, ESWT can be done.[2]

Extracorporeal shock wave therapy (ESWT) one of the physical therapy modality for the treatment of Achilles tendinopathy. The principles on which ESWT acts include pain relief, tissue regeneration, destruction of calcifications. Randomised controlled trials showed significant improvement in clinical results of ESWT for insertional achilles tendinopathy with or without Haglund's deformity.[3]

Local injection of corticosteroid for treatment of achilles tendinopathy is controversial. Studies have demonstrated that exposure to corticosteroid causes cellular degeneration, decrease in cell proliferation rate, and reduction in cellular capacity for tendon repair.[4] There were case reports reporting tendon rupture following injection of corticosteroids.[5,6,7]

Image-guided retrocalcaneal bursitis corticosteroid injections provide a high rate of short- term efficacy and carry <2% risk of subsequent Achilles tendon rupture. Image-guided injections may be considered an adjunct to physical therapy for retrocalcaneal bursitis in patients recalcitrant to conservative therapies.[8]

Another case report on diagnosis and treatment of Haglund syndrome stated that using ultrasound guided injection for retrocalcaneal bursitis is a simple, reliable method of ensuring accurate delivery of medication into the bursa and avoiding intratendinous injection.[9]

Orthobiologics are recent advances in the treatment of various musculoskeletal (MSK) disorders, with good results attributed to the regenerative capacity of biologically active components present in them.[10]

Platelet-rich plasma (PRP) is an autologous blood product in which viable and intact platelets are concentrated in small volume. Therapeutic PRP concentration contains about 3- 8 times the normal circulating levels (~1 million/ml). Platelets contain several growth factors, cytokines and chemokines, all packed in macrophage vesicles as granules or lysosomes.[11] Rationale for PRP therapy is that an injection of concentrated platelets at sites of injury may initiate tissue repair via the release of many biologically active factors (growth factors, cytokines, lysosomes) and adhesion proteins. It has anti-inflammatory role due to the presence of hepatic growth factors (HGFs) through inhibition of NF-kB (nuclear factor kappa-light-chain-enhancer of activated B cells).This study aims to compare the effectiveness of ESWT, a conventional physical therapy procedure and ultrasound guided injection of PRP at the multiple sites injection around Achilles tendon for Haglund syndrome.

Materials and Method:-

This study is a randomized controlled trial, done in Department of Physical Medicine and Rehabilitation, Regional Institute of Medical Sciences, Imphal for a period of 2 years among patients presenting with pain and/or swelling around the back of ankle joint attending Out Patient Department (OPD) of PMR, RIMS Imphal during the study period.

Inclusion criteria of my study were patient with posterior heel pain, Clinical findings of retrocalcaneal bursitis, paratendinitis of achilles tendon and achilles tendinopathy, radiograph finding of heel lateral in projection showing dorsal calcaneal heel spur, and patients in age group of 18-50 years.

Patient with foot deformity, thrombocytopenia (less than 1.8 lakhs /cumm), hypofibrinogenemia and patient on anticoagulation medications, acute and chronic infections, arthritis of ankle joint, chronic liver disease were excluded from the study.
Sample size was calculated using the formula

$$N = (Z\alpha + Z\beta)^2 (S_1^2 + S_2^2)/(m_1 - m_2)^2$$

Where, $Z\alpha = 1.96$ at 5% level of significance , $Z\beta = 1.96$ at 95% power. Taking into consideration the study conducted by Wu et a[3] in 2016, sample was calculated accordingly as, N=11, giving a total sample size of 22 patients.
The approval of the Research Ethics Board, Regional Institute of Medical Sciences, Imphal was taken for this clinical study. Privacy and confidentiality of participants were maintained.

Patients presenting with pain and swelling around ankle, attending PMR OPD of RIMS on Mondays and Thursdays meeting the inclusion and exclusion criteria were informed about the nature of the study and informed consent was taken and recruitment done by convenience sampling. Participants were selected based on availability and willingness to take part in the study until sample size of 22.

Patients were allocated into two groups namely, A=intervention group and B=control group by block randomization technique. Randomization was done by one staff nurse. A block size of four was used. Possible treatment allocation within each block are: (i) AABB (ii) BBAA (iii) ABAB (iv) BABA (v) ABBA (vi) BAAB. Using computer generated table, a list of 6 blocks was prepared to reached a sample size of 22. For each selected blocks, there was a sequence of treatment options. The sequence of treatment option in each block was put in an envelope and sealed. Corresponding envelope was labelled 1, 2, 3, 4....upto 22 according to the appearance of treatment allocation in each selected block. The sealed envelope with label 1 was opened only when we had the first eligible patient and the treatment group was allotted to either group A or B. Control group received standard physical therapy treatment i.e. ESW therapy. Whereas in study group ultrasound guided PRP injection was given around the site of inflammation in the posterior aspect of ankle joint at 4 sites.

A single blinding was done in which the assessor was blinded:-
My study variables were – A . Independent variables: 1. Age in completed years 2. Gender 3.Duration of symptoms 4. Intervention that is ESWT or USG guided PRP injection. B. Dependent variables or outcome measures : 1. Pain measured by using Visual analogue scale (VAS) [Appendix 1] 2. Foot and ankle ability measures (FAAM) ADL sub scale[Appendix 2] for improvement in function. VAS is a validated scale for subjective measure of pain. It consists of a 10cm horizontal or vertical line with the two end points representing 'no pain' and 'worst pain ever'. Patients were asked to rate the level of pain they feel by placing a mark on the 10cm line. FAAM -ADL - 21-item Activities of Daily Living Subscale to assess physical function for individuals with foot and ankle related impairments, item is scored on a 5-point Likert scale (4 to 0) from 'no difficulty at all' to 'unable to do'. The reliability for ADL subscale is ICC = 0.89.

Interventions:-
Group A: Patients in Group A received ESWT for 5 sessions once weekly. Each sessions patient received 2000 pulses at rate of 8 pulses per second and intensity of 0.12 mJ/mm^2 patients were positioned in prone and the applicator is applied at the maximum tender point.Group B: PRP was prepared using by using double spin centrifugation, 24 ml of blood was collected in ACD tubes by venepuncture from cubital vein. The tubes were spined at 2400 rpm per minute which is the first spin, after which the clear supernatant that is the plasma is taken out , and put in plain vials and centrifuged again at hard spin that is 3600 rpm to get upper layer of platelet poor plasma and lower layer of platelet rich plasma with platelet concentrates. 1 ml of PRP is procured from each tube to get total of 3 ml PRP.With high frequency linear probe, the achilles tendon insertional area was examined and inflammation around the tendon was localised by change in signal intensity. 3 ml of PRP prepared was injected at 4 sites.

Fig: Blood collected in ACD tubes for centrifugation in Centrifuge machine

Fig: Localisation of injection sites around Achilles tendon using High frequency USG probe

Follow up assessment at 2 weeks and 8 weeks:-
Data was entered and analysed using IBM-Statistical Package for the Social Sciences (IBM-SPSS) version 21 Armonk, NY: IBM Corp. For descriptive statistics mean, median and standard deviation were used. Student's t-test was used to analysed continuous variables and comparison between the group. Categorical variables were be analysed using Chi-square test. A p-value <0.05 was taken as significant.

Results:-

In both the follow up, data were collected and entered in a pre-structured questionnaire. All data were checked for completeness and consistency. It was found that mean age of the study participant was 43.86±7.58, mean duration of disease was 8.7±4.4. In our study females(54.5%) were more affected than male(45.5%).

Table 1. Comparison between baseline outcome measures

	Study group	Control group	p-value*
VAS	6.73±0.9	7.18±0.751	0.21
FAMM ADL	29.36±5.87	31.73±5.49	0.34

***Students t-test**

On comparison of baseline characteristics between the study group and control group, there were no statistically significant difference (p-value<0.05). So we proceeded with analysis of outcome measures.At end of 2 weeks, we found that there were reduction in pain and improvement in function in both the group, mean difference of VAS (3.63±1.12, 1.81±0.60)(p=0.00) and FAAM(12±7.1, 5.9±4.01) (p=0.02). At the end of 8 weeks, there were statistically significant improvement in pain and activities of daily living. VAS (4.45±1.03, 3±0.44)(p=0.00) and FAAM (21.36±6, 10.81±4.678) (p=0.00). Statistically significant improvement between the study and control group was found in both VAS and FAAM at the all follow up.

Table 2: Comparisons of mean changes in VAS between Study and Control Group

	Study group	Control group	p-value*
2 weeks	3.63± 1.12	1.81± 0.6	0.000
8 weeks	4.45± 1.03	3 ±0.4	0.001

***Students t-test**

Table 3: Comparisons of mean changes in FAAM ADL subscale between Study and Control

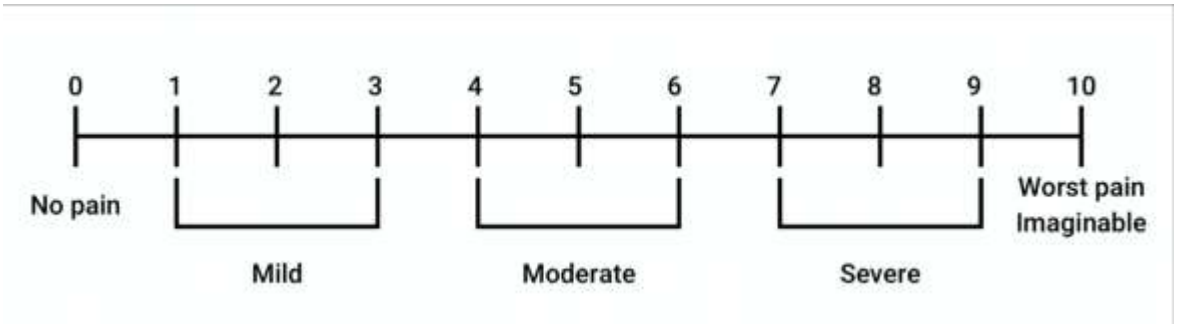
	Study group	Control group	p-value*
2 weeks	12.09 ±7.11	5.9 ±4.01	0.02
8 weeks	21.36± 6.0	10.81± 4.68	0.000

*** Students t-test**

Appendix 1:-

Visual Analog Scale (Vas):-

This pain scale is designed to give a subjective assessment of characteristics and quality of the pain. Please choose the number that you feel matches your current pain.



Appendix 2:-

The Foot And Ankle Ability Measure (Faam) Activities Of Daily Living (Adl) Subscale:-

There are 21 items in the ADL subscale, Each item is scored on a 5-point Likert scale (4 to 0) from 'no difficulty at all' to 'unable to do'. Item score totals, which range from 0 to 84 for the ADL subscale and were transformed to percentage scores.Please answer every question with one response that most closely describes your condition within the past week. If the activity in question is limited by something other than your foot or ankle, mark Not Applicable (N/A). Because of your foot and ankle, how much difficulty do you have with

A. None at all (4)
B. Slight (3)
C. Moderate (2)
D. Extreme (1)
E. Unable to do (0)

F. N/A
1. Standing
2. Walking on even ground.
3. Walking on even ground without shoes
4. Walking up hills
5. Walking down hills.
6. Going up stairs
7. Going down stairs
8. Walking on uneven ground
9. Stepping up and down curbs
10. Squatting
11. Coming up on your toes
12. Walking initially
13. Walking 5 minutes or less
14. Walking approximately 10 minutes
15. Walking 15 minutes or greater
16. Home responsibilities
17. Activities of daily living
18. Personal care
19. Light to moderate work (standing, walking)
20. Heavy work (push/pulling, climbing, carrying)
21. Recreational activities.

Discussion:-

This single blinded, randomised controlled trial done among patients with Haglund syndrome found that the disease is common in middle aged, with females more affected than males which is in conjunction with other literatures. The improvement in pain and functional outcome measures in patients who received USG guided PRP injection, can be attributed to the anti-inflammatory role of activated PRP due to the presence of HGF through inhibition of NF-kB (nuclear factor kappa-light-chain-enhancer of activated B cells) transactivating activity. NF-kB is a homo-/hetero-dimer in which subunit association has different biological significances, dimers containing p65 show transactivating activity. Function of NF-κB is regulation of inflammatory responses, mediating induction of various pro-inflammatory genes in innate immune cells, NF-κB regulates the activation, differentiation and effector function of inflammatory T cells.11 Further there are also studies stating direct analgesic action of PRP through augmentation of certain cannabinoid receptors. Tong S et al have highlighted the analgesic and anti-inflammatory action of PRP in their study.12 There are several other mechanisms through which PRP acts in the treatment of tendinopathy this includes cell proliferation and tissue differentiation, positively influence cell attachment and spreading on the fibrin scaffold, anabolic effects like increasing collagen synthesis, enhances gene expression of collagen type 1 and type III, enhances expression of tendon healing glycoproteins (decorin, tenascin C). Increase level of anti-inflammatory cytokines- IL 10 and TGF beta. In our study there were no immediate post injection complications, double spin PRP has reduced amount of leukocyte, and leukocytes may negatively affect the anabolic effects14 leading to post injection flaring up of inflammation. The use of ultrasound for localization of inflamed tissues and giving under ultrasound guidance increased the accuracy of drug delivery to the targeted areas.8 The limitation of the study is the short follow up period. Further imaging modalities can be use in follow up of the patients to evaluate the structural changes after interventions.

Conclusion:-

From our study we can conclude that ultrasound guided double spined PRP injection around achilles tendon as treatment modality for Haglund syndrome is more effective than ESWT. It reduces pain and improve the functional activities of patients.

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