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ORIGINAL ARTICLE

COMPARATIVE EFFECTS OF ULTRASONIC THERAPY V/S SHOCKWAVE THERAPY IN PATIENTS WITH PIRIFORMIS SYNDROME: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background of the study: Piriformis Syndrome (PS) is a neuromuscular disorder characterized by irritation or compression of the sciatic nerve by the piriformis muscle, often resulting in buttock pain and radiating sciatica-like symptoms. It is a significant cause of non-discogenic sciatica and often leads to considerable pain and functional limitations. Conservative management of PS primarily involves physical therapy modalities, manual techniques, stretching, strengthening exercises, and therapeutic modalities like Ultrasonic Therapy (UST) and Shockwave Therapy (SWT). This study aims to evaluate and compare the clinical effects of UST and SWT on pain intensity and functional disability, in individuals diagnosed with Piriformis Syndrome. **Methodology:** A randomized controlled trial (RCT) study design was used on participants of two groups, 10 patients in each group. Each intervention was administered for a period of 2 weeks, with sessions scheduled 3 times per week. In addition to the primary intervention, both groups received self-stretching of piriformis muscle. Pain Intensity using Visual Analogue Scale (VAS) and Functional Disability using Lower Extremity Functional Scale (LEFS) were evaluated on the first day and after 2 weeks. For between-group comparison Mann-Whitney U test were used for statistical analysis. **Result:** Statistically significant improvements were observed in both the outcome measures in the SWT group compared to the UST group, with SWT having higher mean ranks in both VAS (14.85) and LEFS (15.50) scores ($p < .001$). **Conclusion:** This study concludes that Shockwave Therapy demonstrates greater efficacy in reducing pain and improving functional outcomes than Ultrasonic Therapy.

Keywords: Piriformis Syndrome, Ultrasonic Therapy, Shockwave Therapy, Pain, Functional Disability, Visual Analogue Scale, Lower Extremity Functional Scale, Neuromuscular Disorders.

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INTRODUCTION

Piriformis syndrome is a neuromuscular condition that arises from the compression or irritation of the sciatic nerve by the piriformis muscle, leading to characteristic symptoms such as pain, numbness, tingling, and discomfort in the buttock region and along the course of the sciatic nerve. While it accounts for a small proportion of all sciatica cases—estimated at approximately 5–6%—its impact on physical function and quality of life can be profound.[1] This syndrome is often misdiagnosed due to overlapping symptoms with more common lumbar spine pathologies such as herniated discs and lumbar radiculopathy.

Anatomically, the piriformis muscle originates from the anterior surface of the sacrum, traverses the greater sciatic notch, and inserts into the greater trochanter of the femur. Functionally, it plays a key role in external rotation, abduction, and stabilization of the hip joint.[2] The sciatic nerve typically exits the pelvis inferior to the piriformis muscle, but in some individuals, it may pass through or above the muscle, contributing to potential nerve entrapment. Notably, this anatomical variation is seen in approximately 16% of the general population but does not consistently correlate with symptoms, rendering its clinical significance uncertain.[3]

Piriformis syndrome is believed to affect up to 17% of individuals with chronic low back pain.[4] However, the absence of universally accepted diagnostic criteria makes it difficult to ascertain true prevalence rates. The condition appears to be more common in women than men, possibly due to differences in pelvic anatomy, hormonal influences, and biomechanics.[5]

The etiology of piriformis syndrome is multifactorial, involving traumatic injury, muscle overuse, anatomical anomalies, postural and biomechanical dysfunctions, and, occasionally, direct compression from tumors or hematomas.[1] These diverse etiological factors, coupled with nonspecific clinical symptoms, present diagnostic challenges for clinicians. Typical features include buttock pain exacerbated by sitting or activities such as climbing stairs, tenderness over the piriformis muscle, and a positive FAIR (Flexion, Adduction, and Internal Rotation) test. However, these signs may also be present in other conditions, necessitating differential diagnosis through imaging modalities and physical examination.

Traditional treatment approaches begin conservatively with rest, activity modification, anti-inflammatory medications, and physiotherapy. Physical therapy focuses on relieving muscle tightness and improving hip mechanics through targeted stretching, strengthening exercises, and manual therapy.[2] For cases unresponsive to conservative measures, interventions such as corticosteroid injections, botulinum toxin, or surgical release may be considered.[6]

Among conservative treatments, therapeutic ultrasound (UST) and extracorporeal shockwave therapy (ESWT) have gained attention due to their non-invasive nature and potential efficacy. Therapeutic ultrasound operates using high-frequency sound waves that penetrate deep into tissues to produce thermal and mechanical effects. These effects include increased local circulation, improved collagen elasticity, reduction of muscle spasms, and promotion of tissue repair. Several studies have demonstrated the efficacy of ultrasound therapy in reducing pain and improving range of motion in musculoskeletal disorders such as tendinopathies, myofascial pain syndrome, and chronic back pain.[7,]

Conversely, ESWT utilizes high-energy acoustic waves transmitted through the skin to the affected area, where they generate mechanical stress, microtrauma, and cavitation. These biological processes promote angiogenesis, disrupt pain signaling, enhance collagen synthesis, and release myofascial trigger points.[9] ESWT has shown promise in treating calcific tendinitis, plantar fasciitis, and chronic trigger points, making it a potentially valuable tool in addressing piriformis syndrome.[8]

Despite the widespread use of both UST and ESWT in musculoskeletal rehabilitation, head-to-head comparisons in piriformis syndrome are limited. Most existing research focuses on their individual applications in related conditions, such as gluteal tendinopathy or lumbar radicular pain. This highlights a significant gap in the literature regarding their relative efficacy and optimal clinical protocols for piriformis syndrome specifically. Therefore, comparative studies are urgently needed to inform evidence-based treatment choices and improve outcomes.

In addition to these modalities, piriformis stretching exercises form an essential component of therapy. These stretches, typically performed with the hip flexed above or below 90 degrees, help reduce muscle tension and relieve pressure on the sciatic nerve. Techniques include supine figure-four stretches, seated hip stretches, and standing hip external rotation exercises. Incorporating these stretches enhances flexibility and muscle relaxation, providing symptomatic relief when used in conjunction with other therapeutic interventions.[1]

In summary, piriformis syndrome remains a complex clinical entity characterized by variable symptoms and challenging diagnosis. While conservative treatments remain the mainstay, emerging therapies such as UST and ESWT offer promising adjuncts, especially when integrated with stretching protocols. Given the current paucity of comparative data, this thesis seeks to explore and evaluate the relative benefits of ultrasonic and shockwave therapies in managing piriformis syndrome. Such an investigation is vital for guiding treatment strategies, refining clinical protocols, and ultimately improving patient outcomes.

Materials And Method

Place of study -This study was conducted in the Physiotherapy Department of Northern Railway Central Hospital, New Delhi. Written informed consent was given by each participant.

Inclusion Criteria

1. Adults aged between 20 and 60 years.

2. Clinical diagnosis of PS based on -

    • Positive FAIR (Flexion, Adduction, and Internal Rotation) test.

    • Tenderness over the PM.

3. Duration of symptoms for at least 4 weeks.

4. Able to give informed consent and comply with treatment and follow-up protocol.

Exclusion Criteria

1. History of hip surgery, trauma, or fracture.

2.Neurological disorders (e.g., Multiple sclerosis, radiculopathy)

3. Pregnancy or lactation.

4. Presence of malignancy or infection in pelvic region.

5.Implanted pacemakers or other contraindicated electronic devices (for SWT)

Instrumentation

1. Shockwave Therapy Equipment: Physiotur Symphony (Germany) ESWT device (11)

2. Ultrasonic Therapy Equipment: BTL 4825s (Czech Republic), 1 MHz frequency, continuous mode (12)

Recruitment and randomisation-Participants were randomly assigned to either the UST group or SWT group using a computer-generated randomization table. Allocation concealment was maintained using sealed opaque envelopes. An impartial researcher who was not involved in the treatment process carried out the randomization. Written and informed consent was obtained from every patient. For a period of 2 weeks, 20 individuals were gathered and divided into two groups at random.

Intervention

Group A (UST) - Patients received continuous mode therapeutic ultrasonic wave at 1 MHz frequency and 1.5 W/cm2 intensity for 5 minutes over the PM, in alternate days (total 7 sessions).

Group B (SWT) - Patients received radial shockwave therapy using a pressure of 4 bar, 4.5 Hz frequency and 500 pulses per session targeted at the PM, twice in week for 2 weeks (total 4 sessions).

All Patients in both groups received a standardized home exercise program including Piriformis stretching.

Investigation - The following studies were examined in order to verify the diagnosis and severity of pain in PS patients.

1. FAIR (Flexion, Adduction, Internal rotation) test is used for diagnosed PS.

2. Pace Sign is another criterion to diagnose PS.

3. Tenderness (mild to moderate) present over the PM region.

4. Baseline VAS Score is recorded before the investigation to gauge the severity of pain.

5. Baseline Lower Extremity Functional Scale is used to assess functional impairment.

6. General physical examination is performed to determine whether the therapies being utilized are contraindicated

Treatment protocol

Treatment Duration: - 2 weeks (3 sessions per week, total of 6 sessions)

Participants: - Patients diagnosed with PS presenting with pain and functional disability, meeting the inclusion and exclusion criteria

Group A - Ultrasonic Therapy

• Device - Therapeutic Ultrasonic machine

• Frequency- 1 MHz (for deep tissue penetration) • Intensity- 1.0 - 1.5 W/ cm2

Mode – Continuous mode

• Duration - 5 min.

• Application area- Over the Piriformis muscle (posterior gluteal region)

• Positioning - Prone with pillow support under abdomen

Group B - Shockwave Therapy

• Device - Radial Shockwave Therapy unit

• Energy flux density- 0.1-0.3 mJ/mm2

•Frequency-4.5Hz• Number of shocks - 500 pulse/ session

• Duration- 5 min.

•Application area - Trigger points and along the Piriformis muscle

• Positioning - Prone or side lying

Additional Physiotherapy Intervention for both group

•Piriformis muscle stretching. sets for 30 sec. Hold, 3 repetitions thrice a day.

• Postural advice and ergonomic education.

Outcome Measure

1. Pain intensity assessed using the VAS.

2. Functional activity assessed using Lower Extremity Functional Scale.

Data Analysis - The sample size was estimated using G* power 3.1 software for a two tailed independent t-test comparing UST and SWT on primary outcome measure (pain intensity on VAS).

Parameter Used

• Alpha - 0.05

• Power - 0.80

• Effect size (Cohen's d) - 1.2 (large), based on previous studies evaluating the effect of SWT and UST in musculoskeletal conditions such as Myofascial pain and Piriformis Syndrome.

Calculation Result

• Required sample per group - 10

• Total sample size - 20 participants.

This sample size is adequate to detect a large treatment effect (d=1.2) with 80% power at a 5% significance level. A larger sample may be needed to detect smaller effect sizes or to generalized findings, but this study serves as a controlled trial to examine the clinical significance and feasibility of the intervention.

Statistical Analysis - Version 30.0 of the Statistical Package for the Social Sciences (SPSS) was used to analyze all of the data. The demographic and baseline clinical characteristics of the individuals in both groups were compiled using descriptive statistics, such a as mean, standard deviation, frequencies, and percentages. The Shapiro - Wilk Test was used to determine whether continuous variable was normal before inferential statistical analysis was performed. Tests were either parametric or non- parametric, depending on how the data was distributed.

RESULT AND OBSERVATION

The collected data were analyzed using appropriate statistical tests based on distribution and nature of variables. The outcomes are presented in the form of tables, graph, and comparative summaries to illustrate both within groups and between group difference before and after the intervention.

All analysis was performed using IBM SPSS Statistics (version30.0). Descriptive statistics were calculated for all outcome measures. Due to violations of normality assumptions (Shapiro - Will tests: VAS change p=0.002; LEFS change p= 0.012), nonparametric tests were employed.

1. Within-group comparison -- (pre vs. post treatment) were analyzed using Wilcoxon signed - rank tests.

2. Between-group comparison (UST vs. SWT) were analyzed using Mann - Whitney U tests.

3. Effects sizes were calculated as:

$r = Z/\sqrt{N}$ for Wilco on tests.

$r=Z/\sqrt{(n1+n2)}$ for Mann- Whitney tests

The present study included a total of 20 participants, with 10 subjects in each intervention group: Ultrasound Therapy (UST) and Shock Wave Therapy (SWT). The aim was to evaluate and compare the effectiveness of both treatments in terms of pain reduction and functional improvement.

Descriptive statistics revealed that the mean Visual Analogue Scale (VAS) score reduced from 7.60 ± 0.754 at baseline to 2.85 ± 0.875 post-treatment, indicating significant pain relief. Similarly, the Lower Extremity Functional Scale (LEFS) score increased from 28.25 ± 1.943 to 60.00 ± 4.588 after treatment, suggesting marked improvement in physical function.

Normality testing using the Shapiro-Wilk test indicated that the change scores for both VAS ($p = .002$) and LEFS ($p = .012$) were not normally distributed. Despite this, paired and independent t-tests were used, considering the robustness of parametric tests and the small sample size.

For between-group comparison, the Mann-Whitney U test showed significantly greater improvement in the SWT group compared to the UST group, with SWT having higher mean ranks in both VAS (14.85) and LEFS (15.50) scores ($p < .001$).

Within-group analysis using the Wilcoxon Signed Ranks test revealed statistically significant changes in both groups, with all participants showing decreased VAS scores and increased LEFS scores post-treatment ($p < .001$). The absence of ties or opposite changes further supports the effectiveness of the interventions.

Overall, while both UST and SWT demonstrated beneficial effects, SWT was found to be significantly more effective in reducing pain and improving functional outcomes in patients. These results highlight the potential of SWT as a superior treatment modality for musculoskeletal conditions affecting the lower extremity.

DISCUSSION

Overview of the study - This randomized controlled trial (RCT) was conducted to evaluate and compare the effectiveness of Ultrasound Therapy (UST) and Shockwave Therapy (SWT) in the management of Piriformis Syndrome, focusing specifically on pain reduction and functional improvement. Piriformis Syndrome, characterized by sciatic nerve irritation due to the compression from the piriformis muscle, often leads to significant pain and functional limitations.[1]As such, effective and evidence-based physiotherapeutic interventions are essential for improving patient outcomes.[2] The outcome in this study were measured using the Visual Analogue Scale (VAS) for pain intensity and the

Lower Extremity Functional Scale (LEFS) for assessing functional disability.[24]

Key Findings - The results from the trial clearly demonstrated that both UST and SWT significantly reduced pain and improved function in patients diagnosed with Piriformis Syndrome. However, SWT was found to be more effective than UST, with statistically significant improvements observed in both pain scores and functional outcomes at mid and post-intervention time points.[9,25]

1. Pain Reduction (VAS Scores)

The baseline VAS mean score was 7.60 ± 0.754, which dropped to 2.85 ± 0.875 post-intervention, indicating a marked reduction in perceived pain across both groups. The Wilcoxon test confirmed this change to be statistically significant ($Z = -3.978$, $p < 0.001$). However, between-group comparisons using Mann-Whitney U Test showed that SWT (mean rank = 14.85) led to a significantly greater reduction in pain than UST (mean rank = 6.15), with $U = 6.500$ and $p < 0.001$.(25,9)

These findings align with prior research demonstrating SWT's ability to target deep muscular structures and disrupt myofascial trigger points more effectively than UST. SWT's mechanical pressure waves likely exert a stronger neuromodulatory and regenerative effect on the sciatic nerve's entrapment zone and surrounding soft tissue.[8]

2. Functional Improvement (LEFS Scores)

Similarly, functional scores improved from a baseline mean of 28.25 ± 1.943 to 60.00 ± 4.588 post-intervention. The Wilcoxon test showed a statistically significant improvement ($Z = -3.929$, $p < 0.001$). In the between-group analysis, the SWT group (mean rank = 15.50) outperformed the UST group (mean rank = 5.50), with a U value of 0.000 and $p < 0.001$.(26)

Functional gains in the SWT group can be attributed to enhanced tissue repair, neovascularization, and decreased muscle tightness, which may have resulted in better biomechanics and reduced sciatic nerve irritation during daily activities.[9,25]

Normality and Statistical Rigor

Although Shapiro-Wilk tests indicated that the change scores were not normally distributed (VAS: $p = 0.002$; LEFS: $p = 0.012$), nonparametric tests were appropriately used, increasing the reliability of the statistical conclusions in light of the small sample size. Notably, while parametric tests are often considered robust to mild violations of normality, nonparametric methods are more appropriate when distributional assumptions are clearly violated.[9]

Participants treated with SWT experienced a greater reduction in VAS scores compared to those in the UST group. This finding is consistent with existing literature that attributes SWT's superior performance to its ability to penetrate deeper into soft tissues and modulate pain pathways more effectively,[8,27] SWT is believed to exert its effects through mechanical stimulation that promotes biological healing responses, including the reduction of pain mediators and modulation of nociceptive signals. In contrast, while UST has known thermal and mechanical effects that promote healing and reduce inflammation, its depth of penetration and neuromodulatory effects may be less profound than those of SWT.

Interpretation of Results - The superior outcomes observed in the SWT group suggest that SWT may exert more comprehensive physiological effects compared to UST. The probable mechanisms underlying SWT's enhanced effectiveness include:

• Enhanced local blood circulation: Improved perfusion contributes to the removal of inflammatory metabolites and better oxygenation of tissues.

•Reduction of muscle spasm: Mechanical waves delivered through SWT may help relax the piriformis muscle, reducing pressure on the sciatic nerve.[9]

•Modulation of nociceptors: SWT may desensitize pain receptors and reduce levels of inflammatory mediators, thereby lowering the perception of pain.[8]

On the other hand, UST, though effective in reducing symptoms, may lack the depth and regenerative stimulation needed for more robust recovery. Its benefits may be more limited to superficial thermal effects and may not reach the deeper layers of tissue affected in Piriformis Syndrome.[28]

Comparison with Previous Studies - The findings of this study align well with the growing body of evidence supporting the efficacy of SWT in musculoskeletal conditions. Previous studies have reported SWT's superiority in managing tendinopathies, myofascial pain syndromes, and other soft tissue disorders.[9,27] Its ability to stimulate neovascularization, collagen production, and anti-inflammatory effects has been well-documented.[8] Conversely, although UST remains a staple in physiotherapy practice and is supported by evidence for its analgesic and tissue-healing properties, it often falls short when compared to more modern modalities such as SWT in terms of long-term efficacy and depth of action.[26,28]

This consistency with prior research enhances the credibility of the current findings and supports the growing recommendation for SWT as a frontline therapeutic modality in cases of Piriformis Syndrome, particularly when faster or more substantial improvements in symptoms are desired.

Clinical Implications - The results of this study have important clinical implications. Given the statistically and clinically significant superiority of SWT in both pain reduction and functional improvement, it is recommended that SWT be considered a preferred modality in the management of Piriformis Syndrome. Clinicians should consider incorporating SWT into their treatment protocols, particularly for patients who present with moderate to severe symptoms or for whom traditional therapies like UST have not provided sufficient relief.[9] Moreover, the rapid onset of symptomatic relief observed with SWT may enhance patient satisfaction and adherence to therapy.[27]

Limitations of the Study - Despite the promising results, this study had several limitations that must be acknowledged:

•Small sample size: The limited number of participants restricts the generalizability of the findings. While statistically significant differences were observed, a larger sample would provide more robust evidence and reduce the margin of error.

•Short follow-up period: The current study assessed outcomes only up to the immediate post-intervention phase. Long-term effectiveness and recurrence rates of symptoms remain unknown. Future studies should incorporate extended follow-up durations to assess the sustainability of treatment effects.[25]

Recommendations for Future Research - To build upon the findings of this study, the following recommendations are proposed:

•Larger, multicentre trials should be conducted to confirm the effectiveness of SWT over UST in diverse populations and clinical settings.[9]

•Long-term follow-up studies are necessary to evaluate the duration of therapeutic benefits and to determine whether maintenance treatments are required.[8]

•Exploration of combination therapies, such as integrating SWT with manual therapy or therapeutic exercise, could be beneficial and may offer synergistic effects.[27]

•Comparative cost-effectiveness analyses would help in determining the feasibility of SWT in resource-limited clinical environments.[29]

CONCLUSION

This randomized controlled trial was undertaken to compare the effectiveness of Ultrasound Therapy (UST) and Shockwave Therapy (SWT) in managing Piriformis Syndrome (PS), a neuromuscular condition characterized by pain and functional impairment resulting from sciatic nerve entrapment. The primary outcome of the study was a reduction in pain intensity, measured using the Visual Analog Scale (VAS), while the secondary outcome focused on improvement in physical function, assessed through the Lower Extremity Functional Scale (LEFS).

A total of 20 patients diagnosed with Piriformis Syndrome participated in the study, with 10 patients in each group. The data obtained through pre- and post-intervention assessments underwent appropriate statistical analysis, including Wilcoxon Signed-Rank Test for within-group comparisons and Mann-Whitney U Test for between-group comparisons, in view of the non-normal distribution of the change scores.

Therapeutic Efficacy and Group Comparisons

The findings revealed that both UST and SWT were effective in significantly reducing pain and improving function in individuals with PS. However, a more pronounced therapeutic benefit was observed in the SWT group compared to the UST group.

The overall mean VAS score dropped from 7.60 ± 0.754 at baseline to 2.85 ± 0.875 post-treatment, indicating substantial pain relief. However, the SWT group showed significantly higher mean ranks (14.85) than the UST group (6.15) in the Mann-Whitney test, confirming superior pain reduction with SWT ($U = 6.500$, $p < 0.001$).

LEFS scores improved significantly from 28.25 ± 1.943 to 60.00 ± 4.588 overall. The SWT group again demonstrated greater functional recovery, with a mean rank of 15.50 compared to 5.50 in the UST group, a difference that was statistically significant ($U = 0.000$, $p < 0.001$).

These results support the hypothesis that SWT is more effective than UST in treating both the pain and functional limitations associated with Piriformis Syndrome.

Mechanistic Insights and Clinical Implications is the superior outcomes with SWT may be attributed to its mechanical and biological effects on soft tissues. SWT delivers high-energy acoustic waves that promote neovascularization, tissue regeneration, and the breakdown of fibrosis and calcifications[9,29]

These mechanisms are particularly beneficial in cases like PS, where chronic muscle tightness, myofascial trigger points, and nerve compression are common.[30] Additionally, SWT has been associated with neuromodulatory effects, reducing peripheral nerve hypersensitivity and improving local circulation.[8] In contrast, while UST also improves blood flow and has thermal and micro-massage effects[7], its depth of penetration and regenerative potential are relatively limited compared to SWT. This may explain the lower magnitude of clinical improvement observed in the UST group.

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