

Integrating Ultrasound-Guided Multifidus Injections with Repeated Peripheral Magnetic Stimulation for Low Back Pain: A Feasibility Study

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Background: Low back pain is a globally prevalent musculoskeletal issue. Repetitive peripheral magnetic stimulation (rPMS) is emerging as a promising modality for managing musculoskeletal pain, while ultrasound-guided lumbar facet/multifidus injections are a potential therapeutic option for low back pain. This study explores the feasibility of combining these two treatments for managing low back pain.

Materials and Methods: Ultrasound-guided injections were administered using 5 mL of 50% dextrose and 5 mL of 1% lidocaine. Bilateral injections targeted the L4/L5 and L5/S1 facet joints with 1 mL at each site, and the remaining 8 mL was distributed over the multifidus muscles using peppering techniques. Following injections, rPMS therapy was conducted with the TESLA Stym[®] device, targeting the bilateral lumbosacral region over 12 sessions. Pain intensity was measured using the visual analog scale (VAS), and disability was assessed with the Oswestry disability index (ODI) at baseline, after six sessions, and after 12 sessions of rPMS.

Results: Three participants were enrolled. Baseline VAS and ODI scores were 8.33 ± 0.29 cm and $49.63 \pm 1.28\%$, respectively. After six rPMS sessions, VAS and ODI scores changed to 4.33 ± 3.75 cm and $21.48 \pm 19.42\%$, respectively. After 12 sessions, VAS decreased to 0.83 ± 1.44 cm and ODI to $5.19 \pm 8.98\%$. Significant differences were observed between baseline and final assessments.

Conclusion: Combining ultrasound-guided lumbar facet/multifidus injections with rPMS shows promise for treating low back pain. However, long-term efficacy and comparison with conventional treatments require further investigation through prospective randomized controlled trials.

Keywords: Magnetic field therapy, lumbar vertebrae, paraspinal muscles, ultrasonography, interventional procedures

Introduction

Low back pain (LBP) is a prevalent musculoskeletal issue worldwide.¹ Its age-standardized point prevalence in 2017 was 7.5%, with the number of affected individuals reaching approximately 577 million. This condition tends to escalate with age, peaking notably between 80 to 89 years of age. Various environmental and individual factors have been linked to heightened risk of LBP such as older age, poor general health like smoking, physical stressors such as vibration, and psychological stress including depression.² LBP can stem from diverse causes including muscle strain, disc problems, spinal stenosis, arthritis, or traumatic injuries. Prognostic factors for nonspecific chronic LBP have been reported as maladaptive behaviors, anxiety, functional limitations during episodes, smoking, and physical labor.³ Non-pharmacological treatments like exercise therapy and physiotherapy are recommended as initial approaches, particularly for chronic LBP or high-risk patients.⁴ Cognitive behavioral therapy, often combined with physical therapy, is suggested for improving pain management. Pharmacological interventions encompass oral treatments, topical lidocaine patches, and spinal epidural injections.⁴ Despite the efficacy of various treatment modalities, a significant proportion of patients remain resistant to these strategies.

Repeated peripheral magnetic stimulation (rPMS) shows promise as an effective treatment for various types of musculoskeletal pain. It involves the application of a rapidly pulsed, high-intensity magnetic field to peripheral areas of the body, excluding the brain.⁵ Unlike electrical stimulation, rPMS bypasses the need to use electrodes for delivering electric current through the skin to the target tissue. The equipment typically comprises a high-current pulse generator and a stimulating coil. rPMS has shown efficacy in treating conditions like myofascial pain syndrome, traumatic brachial plexopathy, post-traumatic peripheral neuropathic pain, and spasticity.⁵ Recent studies, included in a 2023 meta-analysis, highlight its potential in alleviating LBP.⁶ Moreover, advancements in ultrasound (US) imaging allow for precise visualization of the musculoskeletal structures in the thoracic and lumbar spine.⁷ Given the involvement of lumbar facet joints and adjacent muscles like the multifidus in LBP, US-guided multifidus injections seem to have a potential therapeutic avenue.⁸

Chen et al⁸ compared the effects of US-guided prolotherapy with 5% dextrose in water in the multifidus muscle to US-guided mechanical needling and sterile water injections for treating lumbar spinal stenosis. They evaluated LBP, leg pain, and gait ability using the Visual Analogue Scale (VAS) and walking distance at six different time points. Of the 211 older patients with lumbar spinal stenosis, 104 received US-guided mechanical needling and sterile water injections over four weeks, while 107 received a single session of dextrose injection into the multifidus muscles. Both intervention groups showed significant improvements in chronic LBP, radiating pain, and walking ability at 1 and 3 months post-treatment compared to baseline. The authors concluded that prolotherapy with dextrose in the multifidus muscle has a moderate effect lasting up to three months.

To date, no research has explored the feasibility of combining ultrasound-guided lumbar facet joint or multifidus injections with rPMS for LBP. While US-guided injections provide targeted pain relief, rPMS offers a broader effect on pain relief beyond the site of local injection. Given these complementary mechanisms, we hypothesized that combining these therapies could result in rapid and sustained relief of LBP. This study was designed to address this gap and investigate the potential synergistic effects of these modalities in pain management.

Materials and Methods

Participants and Study Flow

Participants were sourced from the outpatient clinic of the Department of Physical Medicine and Rehabilitation at National Taiwan University Hospital, Bei-Hu Branch. The eligibility of all candidates who completed the baseline questionnaire concerning LBP was assessed. The study utilized retrospective patient data from the clinic's registry, which did not require approval from the hospital's institutional review board for a case report involving three or fewer cases. According to the institutional review board's regulations for a case report, patient informed consent was not required for the retrospective review of electronic medical records, as confidentiality was maintained in accordance with the Declaration of Helsinki. Based on a meta-analysis by Diao et al in 2023,⁶ patients with acute or chronic low back pain, lumbosacral spondylotic changes, and lumbar radiculopathy are potential candidates for rPMS treatment. Therefore, our inclusion criteria encompassed (1) age exceeding 18 years, (2) experiencing non-specific LBP for a minimum of six weeks within the past 12 months, and (3) provision of available data for analysis. Exclusion criteria consisted of back trauma/surgery within the preceding three months. A control group would not be included for analysis if the required scoring scales were lacking. Enrolled participants underwent US-guided injection for bilateral lumbar facet joints and adjacent multifidus muscles. Subsequently, they received 12 sessions of rPMS over a 6-week period. Assessments were done at baseline, after six and 12 sessions of rPMS (Figure 1).

Application of rPMS

rPMS therapy involved the utilization of the TESLA Stym[®] device (Iskra Medical d. o.o., Slovenia) which is equipped with a spacious movable applicator specifically designed to target the bilateral lumbosacral region symmetrically. The simulation protocol was adapted from the study by Radaković et al,⁹ which used the same rPMS machine as ours to treat 28 male patients with sciatica. This treatment regimen relied on a tailored combination of amplitudes and frequencies, known as the "Chronic Pain Back Pelvic II" program, operating in accordance with Faraday's law of magnetic induction.

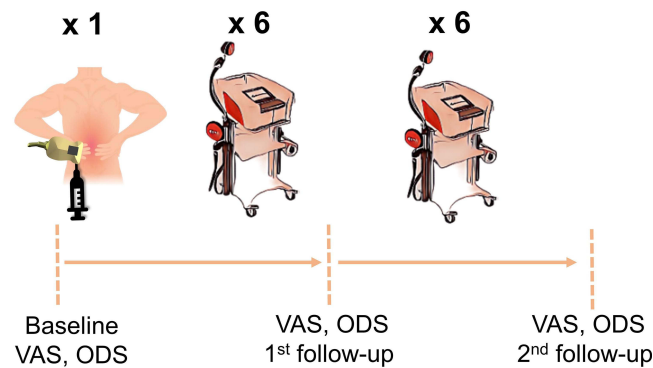


Figure 1 Flowchart for implementing interventions and measuring outcomes of studies.

Abbreviations: VAS, visual analogue scale, ODI, Oswestry disability index.

Through the application of magnetic pulses, nerves were stimulated, and paraspinal muscle activity was modulated - resulting in the repeated activation of motor nerve fibers and motor end plates, thus enhancing muscle strength and endurance. The stimulator generated symmetric magnetic gradients of up to 2.5 Tesla/sec. Each rPMS treatment session lasted for 20 minutes, conducted three times weekly over four consecutive weeks. The stimulus intensity level commenced at 20% of the maximal stimulator output and increased gradually by 2%. The final intensity was adjusted to the maximum level that elicited appropriate contraction of the paraspinal muscles while remaining within the patient's tolerable range.

US-Guided Injection

A convex transducer (i10CX1) operating at a center frequency of 5.0 MHz, integrated within the Aplio i600 platinum platform (Canon Medical Systems, Tokyo, Japan) was employed to guide the injections. Participants were positioned prone, with a pillow placed over their abdominal region for comfort. Scanning commenced from the midline, where the peak of the spinous process and the median sacral crest were clearly visualized. Subsequently, the transducer was adjusted laterally to observe the laminae, which appeared as straight bone planes separated by the inter-lamina space, represented by the dura and ligamentum flavum.¹⁰ Upon adjusting the transducer laterally, the facet column emerged, characterized by its mountain-range-like structure, with the inferior articular process connecting cranially and the superior articular process connecting caudally. Once the longitudinal plane of the facet column was identified, a 21 G 7-mm NIPRO needle was introduced through an in-plane, caudal to cranial approach. A mixture of 5 mL of 50% dextrose and 5 mL of 1% lidocaine was used. L4/L5 and L5/S1 facet joints were targeted with administering 1 mL of injectate in each, whereby the remaining 8 mL was distributed over the multifidus muscles using peppering injection techniques (Figure 2). If the patient presented bilateral symptoms, bilateral paraspinal muscles would be injected.

Outcome Evaluation

Assessments encompassed VAS to gauge pain intensity and the Oswestry disability index (ODI). The former is a widely recognized method for subjectively evaluating pain intensity.¹¹ Participants indicated their pain level on a scale of 0 to 10 cm, spanning from "no pain" to "worst pain imaginable." The distance from the "no pain" end to their marked point was measured, offering a quantifiable representation of pain intensity.

The ODI comprises ten sections, each targeting various daily activities impacted by LBP, such as lifting, walking, sitting, standing, and sleeping.¹² Respondents rated their degree of disability on a scale from 0 to 5 for each section, where 0 signifies no disability and 5 signifies maximal disability. These scores across all sections were then aggregated to derive an overall disability score, typically ranging from 0 to 50 or expressed as a percentage.

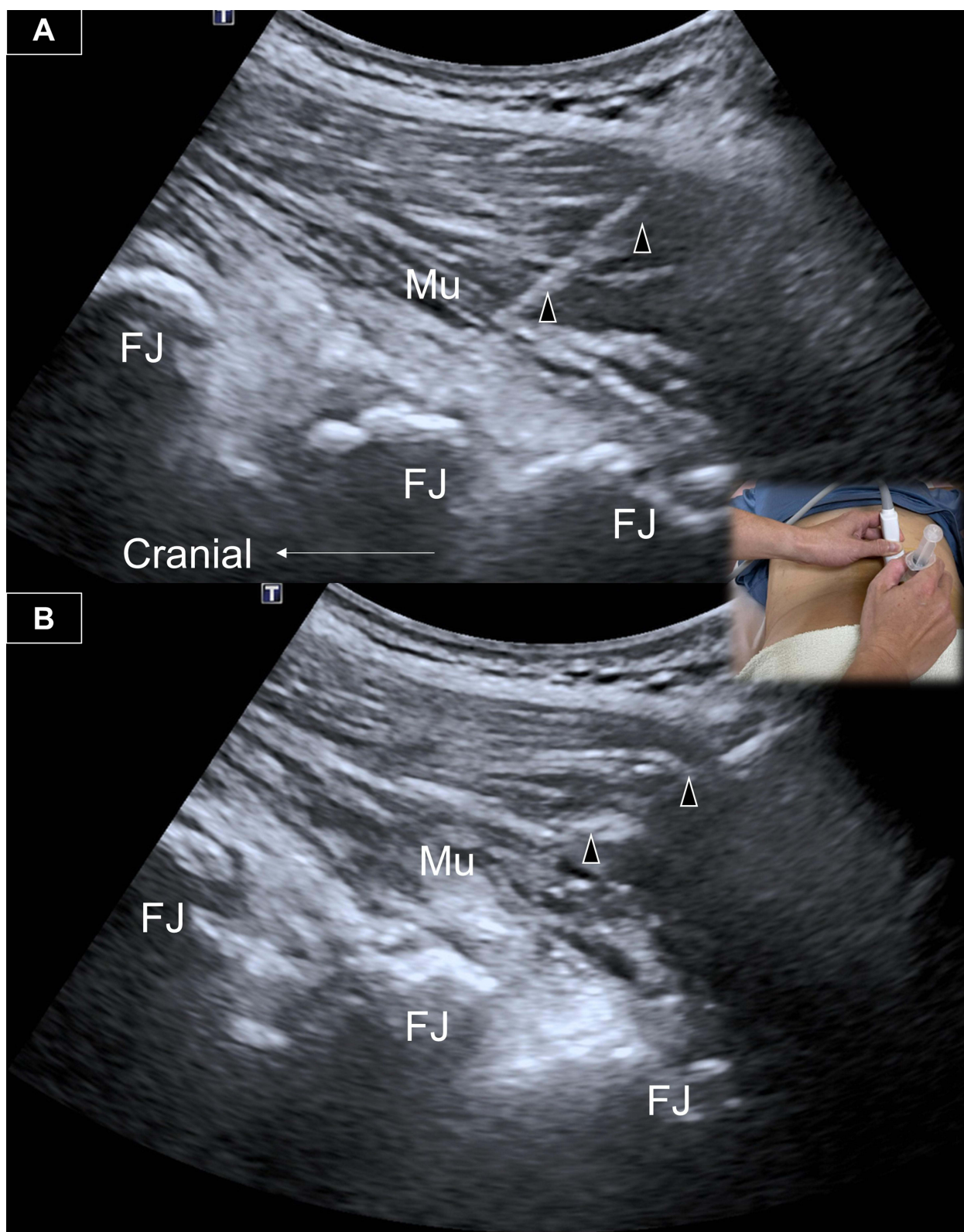


Figure 2 Ultrasound-guided (A) lumbar facet joint (FJ) and (B) lumbar multifidus (Mu) muscle injection. Arrowhead, needle trajectory.

Statistical Analysis

We employed the Shapiro–Wilk test to assess the normality of continuous variables. If the variables followed a normal distribution, we proceeded with univariate analysis using either one-way analysis of variance or the Mann–Whitney

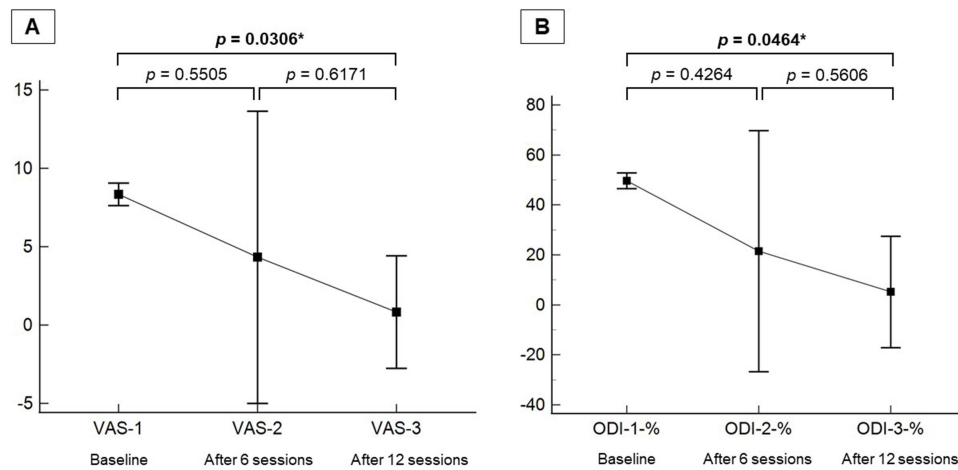


Figure 3 Line graphs showing the changes in (A) visual analogue scale (VAS) and (B) Oswestry disability index (ODI).

Notes * indicates $p < 0.05$.

U-test. For categorical data comparison, the chi-square test was applied, with Fisher's exact test utilized for small cell counts. Repeated measure analysis of variance was employed to compare means across various time points within groups. All statistical analyses were conducted using SPSS 21.0b software, with a significance level set at $P < 0.05$.

Results

Three participants (2 F and 1 M) were enrolled in the study. Their ages ranged from 36 to 72 years, with an average of 56.33 ± 18.45 years (95% confidence interval [CI], 10.51–102.16). Heights varied between 156.3 and 170 cm, averaging 162.10 ± 7.09 cm (95% CI, 144.49–179.71). Body weights ranged from 47 to 61.6 kg, with an average of 51.97 ± 8.34 kg (95% CI, 31.24 to 72.69). Lumbar spondylosis was identified on the plain film in two participants.

Initially, baseline VAS in cm and ODI in percentage were recorded at 8.33 ± 0.29 (95% CI, 7.62 to 9.05) and 49.63 ± 1.28 (95% CI, 46.45 to 52.81), respectively. Following US-guided injections and six sessions of rPMS, VAS and ODI (%) values changed to 4.33 ± 3.75 (95% CI, -4.99 to 13.66) and 21.48 ± 19.42 (95% CI, -26.75 to 69.72), respectively. After an additional six sessions of rPMS, VAS and ODI (%) further decreased to 0.83 ± 1.44 (95% CI, -2.75 to 4.42) and 5.19 ± 8.98 (95% CI, -17.13 to 27.50), respectively (Figure 3). Significant statistical differences were observed for both VAS and ODI (%) between the baseline and final follow-up assessments (Table 1). No side effects were reported during or within three months after the treatment.

Table 1 Clinical Outcome After Peripheral Magnetic Stimulation Treatment

	Patients (n = 3)
VAS (cm)	
Baseline	8.33 ± 0.29^a (7.62 to 9.05)
After 6 sessions	4.33 ± 3.75 (-4.99 to 13.66)
After 12 sessions	0.83 ± 1.44^a (-2.75 to 4.42)
ODI (%)	
Baseline	49.63 ± 1.28^a (46.45 to 52.81)
After 6 sessions	21.48 ± 19.42 (-26.75 to 69.72)
After 12 sessions	5.19 ± 8.98^a (-17.13 to 27.50)

Notes: Scores are given as mean \pm standard deviation (95% confidence interval of mean). ^a Significant difference between baseline and after the 12th session.

Abbreviations: VAS; visual analogue scale, ODI; Oswestry disability index.

Discussion

The results of this preliminary investigation showed that the integration of US-guided facet and multifidus muscle injections with 12 sessions of rPMS significantly decreased LBP and increased the functional performance - without any adverse effects.

In 2023, Diao et al⁶ conducted a comprehensive meta-analysis investigating the effects of rPMS on pain intensity, functional mobility, and kinesiophobia in individuals affected by LBP. Employing a meticulous approach, they systematically scoured databases such as PubMed, Physiotherapy Evidence Database, Embase, Cochrane Library, and Web of Science. Eligible randomized controlled trials meeting specific criteria regarding the population suffering from low back pain, the intervention of rPMS, and outcomes associated with pain intensity, functional mobility, and kinesiophobia were considered for inclusion. Comparisons were drawn between participants subjected to rPMS and those in sham or alternative control groups pertaining to six randomized controlled trials (out of 733 studies) encompassing 139 participants. The findings revealed that rPMS exhibited noteworthy effectiveness in reducing both pain intensity and functional disability when contrasted with sham rPMS or other therapeutic approaches. However, the analysis did not discern any significant variance in kinesiophobia between the studied groups. The authors cautiously concluded that while rPMS may offer promise in alleviating pain intensity and enhancing functional disability among individuals with LBP, the evidence supporting this assertion ranged from very low to low quality. Nonetheless, the impact of rPMS on kinesiophobia remains uncertain based on the available data.

The understanding of mechanisms behind the effects of magnetic stimulation on LBP is yet incomplete. According to the gate-control theory,¹³ the electrical field produced by magnetic stimulation primarily targets large-diameter myelinated A β afferent fibers, hindering the depolarization of smaller A δ and C nerve fibers. This inhibition may trigger descending inhibition, leading to increased central β -endorphin release, hyperpolarization at the motor end plate, and subsequent muscle relaxation, potentially impeding the transmission of pain perception to the brain. Stimulation of large-diameter fibers also has potential in reducing nociceptive signaling in spinal dorsal horns. Furthermore, rPMS offers advantages such as localized targeting and the activation of efferent fibers in mixed nerves, resulting in physiologic muscle contraction without significant discomfort.¹⁴ In patients with LBP, paraspinal muscles might become atrophic,¹⁵ and activation of the atrophic muscles might be helpful to restore their muscle mass. Additionally, when applying rPMS, suprathreshold stimulation operates under the assumption that muscle contraction will activate proprioceptive afferents, thus aiding neuroplasticity.¹⁶ Another plausible explanation involves the immediate activation of a descending inhibitory pathway, possibly by activating brain stem areas like the rostral ventral medulla and periaqueductal gray.⁵

Numerous individuals experiencing LBP often exhibit myofascial trigger points within the paraspinal muscles, particularly the multifidus. Freeman et al¹⁷ emphasized the crucial role of the lumbar multifidus muscles as stabilizers of the trunk. Dysfunction in these muscles strongly correlates with LBP, resulting in pain inhibition originating from the spine. Persistent dysfunction in the lumbar multifidus muscles presents as atrophic replacement by fat, a condition best visualized through magnetic resonance imaging. Hence, administering injections into the multifidus muscle could potentially alleviate LBP.

In 2021, Kanamoto et al¹⁸ conducted a cohort study involving 75 patients diagnosed with acute LBP based on physical and imaging findings. They performed hydro-release of the multifidus muscle at the L4/5 level. Statistical analysis of VAS scores before and five minutes after hydro-release demonstrated significant improvement. The injection technique mirrored that proposed by Chen et al⁸ who advocated an in-plane approach from lateral to medial, enabling sequential targeting of the lumbar facet joint, medial branches, and short axis of the multifidus with a single needle entry portal. In contrast, our adapted method involves inserting the needle along the long axis of the spine to target the multifidus and two levels of the facet joints (L4/L5 and L5/S1). This modification broadens the scope of potential pain sources, leading to enhanced pain relief outcomes. The combination of US-guided lumbar facet/multifidus muscle injection followed by rPMS offers several advantages. Of note, US guidance enables clear identification of the deeply situated multifidus muscle, ensuring safe injection without the risk of injuring intrathecal structures. In areas where muscle fibers are prone to disorganization and exhibit focal hypoechoic echotexture, trigger points are more prevalent and can be effectively relieved through repeated needle release.¹⁹ This process

significantly enhances local blood flow, addressing the energy crisis within the myofibrils associated with myofascial pain.²⁰ Once the energy crisis is resolved, subsequent rPMS can help modify pain perception in the low back region and adjust the local pain threshold. Additionally, the atrophic or inactive paraspinal muscle may potentially be activated or strengthened through rPMS sessions, leading to improved functional recovery from disability caused by LBP.

Moreover, the rationale for administering the injection before rPMS is based on the promptness of treatment effects and the number of sessions required. US-guided injections for affected muscles can result in significant pain reduction after just one session, as shown by a recent narrative review on the use of US imaging and guidance in managing myofascial pain syndrome.²¹ In contrast, rPMS requires multiple sessions to achieve significant benefits for patients with LBP, as demonstrated by the meta-analysis by Diao et al.⁶ Therefore, to provide patients with rapid and sustained pain relief, we first administer US-guided injections for the multifidus muscle, followed by rPMS.

The current investigation is constrained by several limitations. First, the retrospective design had been applied on the present research, whereas recall bias and participant self-selection might be a potential source of bias. Second, the inclusion of only three cases limits the study's representativeness, so the data should be interpreted with caution. Third, the study only includes one treatment (and no control) arm, therefore it cannot exclude pain relief solely to natural recovery. Moving forward, there is a critical need for a prospective randomized controlled trial comparing intervention with a control (or placebo) arm to provide clearer insights. Furthermore, if a randomized controlled trial will be conducted in the future, a sample size calculation is necessary to ensure the adequate power to detect the difference between our developed combination therapy and the controlled treatment.

Conclusion

Utilizing US-guided lumbar facet/multifidus muscle injection alongside rPMS presents a viable approach for the management of LBP. Herewith, assessing the sustained efficacy of this combined therapy in the long term and comparing it with conventional non-operative treatments require prospective randomized controlled trials to offer more definitive insights.

Data Sharing Statement

The data generated or analyzed during the study are available from the corresponding author on reasonable request.

Ethics Approval and Informed Consent

The study utilized retrospective patient data from the clinic's registry, which did not require approval from the hospital's institutional review board (eg National Taiwan University Hospital) for a case report involving three or fewer cases. According to the institutional review board's regulations for a case report, patient informed consent was not required for the retrospective review of electronic medical records, as confidentiality was maintained in accordance with the Declaration of Helsinki.

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Disclosure

The authors report no conflicts of interest in this work.

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