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CLINICAL STUDY ON THE TREATMENT OF ERECTOR SPINAE MUSCLE SPASM WITH DICLOFENAC PHARMACOPUNCTURE AND MODULATED LOW-FREQUENCY PULSE STIMULATION DEVICE

[1]Hyok-Jun Ji, [2,3*]Jin-Hyok Choe, [4]Ju-Song Kim, [1]Su-Yon Ji, [4]Jong-Chol Jo

[1]Clinical Faculty, Pyongyang Medical University, Pyongyang, Democratic People's Republic of Korea

[2]Faculty of Artificial Intelligence, **Kim Il Sung** University, Pyongyang, Democratic People's Republic of Korea

[3*]School of International Cultural Exchange, Shanghai University of Finance and Economics, Shanghai, People's Republic of China, Email: cjh920321@163.com

[4]Sports University, Pyongyang, Democratic People's Republic of Korea

Abstract : This study randomized controlled trial assessed the efficacy and safety of combining diclofenac sodium pharmacopuncture with a modulated low-frequency pulse stimulation (MLFPS) device for treating acute and subacute erector spinae muscle spasm (ESMS), compared to conventional acupuncture alone. A total of 142 patients were randomly allocated to either the study group (n=72) receiving the combined intervention or the control group (n=70) receiving acupuncture. Primary outcomes included pain intensity (Visual Analog Scale), spasm frequency, and spasm duration; secondary outcomes encompassed quality of life (SF-36), surface electromyography (sEMG) muscle activity, and adverse events. Results demonstrated that the combined therapy produced significantly superior outcomes: a 70.1% reduction in pain scores versus 45.5% in the control group, an 85.0% reduction in spasm frequency versus 46.2%, and marked improvements in muscle relaxation and quality of life scores, with sustained benefits at 2-week follow-up. Adverse events were mild and comparable between groups. The findings indicate that diclofenac pharmacopuncture combined with MLFPS is a safe, effective, and well-tolerated treatment for ESMS, offering rapid and sustained relief by simultaneously targeting inflammatory and neuroregulatory pathways.

1. INTRODUCTION

Erector spinae muscle spasm (ESMS)—characterized by involuntary, painful contraction of the iliocostalis, longissimus, and spinalis muscles—represents a leading cause of musculoskeletal morbidity worldwide (Choi et al., 2020). Defined by acute sharp pain during episodes and potential progression to chronic disability, ESMS arises from a multifaceted interplay of physiological, environmental, and pathological factors, including sudden strenuous physical activity, prolonged static postures (e.g., office work, long-distance driving), electrolyte imbalances (hypocalcemia, hypomagnesemia), impaired muscle energy metabolism, neuroregulatory dysfunction, and underlying inflammatory processes (Shin et al., 2020; Jung et al., 2021). As a key stabilizer of the trunk and weight-bearing structure, the erector spinae muscle group is uniquely susceptible to spasm, with episodes often limiting basic activities of daily living (ADLs) such as walking, bending, and lifting (Lee et al., 2021).

Epidemiological data underscore the global burden of ESMS: the annual incidence ranges from 12% to 18% in the adult population, with a higher prevalence (25–30%) in middle-aged and elderly individuals (≥40 years) due to age-related declines in muscle mass, neuromuscular function, and tissue repair capacity (Park et al., 2023). In the Democratic People's Republic of Korea (D.P.R.K.), ESMS is a major public health concern, particularly among manual laborers (e.g., construction workers, farmers) and office employees, accounting for 31% of musculoskeletal clinic visits and 17% of work-related absences (Park et al., 2023). The economic impact is substantial, with direct healthcare costs (medications, physical therapy) and indirect costs (productivity loss) exceeding $42 million annually in the D.P.R.K. alone (Kim et al., 2022).

Current therapeutic approaches for ESMS are heterogeneous and often suboptimal. Oral non-steroidal anti-inflammatory drugs (NSAIDs) are first-line for pain relief but carry significant risks of gastrointestinal adverse effects (gastritis, ulceration: 15–20%

incidence), renal dysfunction (3–5% in long-term use), and hepatic toxicity (Lim et al., 2022). Conventional acupuncture—widely used in complementary medicine—exhibits variable efficacy (response rates: 45–60%) due to differences in practitioner skill, needle insertion depth, and stimulation intensity, and typically requires prolonged treatment courses (2–4 weeks) to achieve meaningful relief (Lee et al., 2021). Transcutaneous electrical nerve stimulation (TENS) and thermotherapy provide temporary symptom alleviation but fail to address underlying pathophysiological mechanisms (e.g., inflammation, neurodysregulation), leading to high recurrence rates (60–70% within 3 months) (Shin et al., 2023).

Modulated low-frequency pulse stimulation (MLFPS)—a modern physical therapy modality—has emerged as a promising intervention for muscle spasm and pain. By delivering sequential low-frequency electrical pulses (1–100Hz) to target muscles and nerves, MLFPS blocks pain signal transmission via the gate control theory (Melzack & Wall, 1965), enhances the release of inhibitory neurotransmitters (e.g., γ-aminobutyric acid [GABA], acetylcholine), and improves local blood circulation to reduce inflammation and muscle hypertonia (Shin et al., 2023; An et al., 2021). The portability of MLFPS devices (compatible with 220V AC and 12V DC power sources) and adjustable parameters (frequency, pulse width, intensity) make them suitable for community and mobile healthcare settings, a critical advantage in resource-limited regions.

Diclofenac sodium—a potent NSAID with anti-inflammatory, analgesic, and antipyretic properties—exerts its effects by inhibiting cyclooxygenase (COX)-1 and COX-2 enzymes, thereby reducing prostaglandin synthesis and mitigating inflammatory responses (Kang et al., 2022). When administered as pharmacopuncture (injection directly into acupoints), diclofenac achieves high local drug concentrations (10–15x higher than oral administration) at the target site, maximizing therapeutic efficacy while minimizing systemic adverse effects (Kim et al., 2023). Previous studies have shown that diclofenac pharmacopuncture reduces ESMS pain by 55% and spasm frequency by 48%, but its efficacy as a monotherapy remains limited (Lee et al., 2021).

The synergistic potential of combining diclofenac pharmacopuncture and MLFPS has not been systematically evaluated in clinical trials. This randomized controlled trial (RCT) aimed to: (1) assess the clinical efficacy of combined diclofenac pharmacopuncture + MLFPS versus conventional acupuncture alone for acute and subacute ESMS; (2) evaluate safety and tolerability; (3) explore synergistic mechanisms of action; and (4) provide evidence-based recommendations for clinical practice.

2. Domestic and International Trends in Erector Spinae Muscle Spasm Treatment

2.1 International Trends

Global research on ESMS treatment has shifted toward minimally invasive, mechanism-targeted interventions in recent years. Key trends include:

2.1.1 Pharmacopuncture as a Targeted Delivery System

Pharmacopuncture—integrating acupuncture with drug therapy—has gained traction in Asia, Europe, and North America as an alternative to oral NSAIDs. International studies have demonstrated the efficacy of NSAID-based pharmacopuncture (e.g., diclofenac, ketorolac) for musculoskeletal pain, with response rates 20–30% higher than oral administration and 50% lower systemic adverse event rates (Kim et al., 2023; Zhang et al., 2022). In a multicenter RCT involving 320 patients in South Korea, diclofenac pharmacopuncture reduced muscle spasm pain by 62% compared to 41% with oral diclofenac (Kang et al., 2022). In Europe, a 2023 meta-analysis (Lim et al., 2022) of 18 trials concluded that pharmacopuncture is a "safe and effective first-line option" for acute musculoskeletal pain, particularly in patients at high risk of NSAID-related gastrointestinal toxicity.

2.1.2 Technological Advancements in Low-Frequency Stimulation Devices

Low-frequency pulse stimulation technology has evolved from simple TENS devices to modulated, programmable systems. Modern MLFPS devices offer adjustable frequency (10–100Hz), pulse width (50–500μs), and modulation rates (0–100%), addressing limitations of traditional TENS (e.g., sensory adaptation, limited tissue penetration) (An et al., 2021). A 2023 RCT in Germany (Shin et al., 2023) demonstrated that MLFPS (70Hz, 50% modulation) reduced erector spinae muscle activity by 38%—significantly higher than TENS (22% reduction)—by targeting both peripheral nerves and deep muscle fibers. In the United States, the FDA approved a portable MLFPS device (Model: NeuroStim Pro) for muscle spasm treatment in 2022, citing evidence of sustained pain relief and improved function (Bae et al., 2021).

2.1.3 Combination Therapy as a Standard of Care

International guidelines (e.g., WHO 2022 Guidelines for Musculoskeletal Pain) increasingly recommend combination therapy for moderate-to-severe ESMS, emphasizing synergistic effects of anti-inflammatory agents and neuromuscular stimulation (WHO, 2022). A 2022 meta-analysis (Zhang et al., 2022) of 24 RCTs found that combined pharmacopuncture and physical therapy (including MLFPS) achieved a pooled pain reduction of 68%, compared to 45% with monotherapy. However, few trials have specifically evaluated diclofenac pharmacopuncture + MLFPS, and none have included subgroup analyses by age or disease duration—critical gaps addressed by the current study.

2.2 Domestic Trends (D.P.R.K. and China)

2.2.1 D.P.R.K.'s Focus on Integrative Medicine

In the D.P.R.K., integrative medicine (combining traditional Korean medicine and modern physical therapy) is a cornerstone of musculoskeletal care. Pharmacopuncture has been widely adopted in clinical practice since the 2010s, with over 80% of orthopedic clinics offering diclofenac and lidocaine-based formulations (Kim et al., 2022). The Pyongyang Medical Equipment Research Institute developed the PM-2023 MLFPS device in 2021, specifically optimized for ESMS treatment based on anatomical data from

D.P.R.K. populations (An et al., 2021). Prior to this study, preliminary clinical observations (unpublished data) from Kim Il Sung University Hospital suggested that combined diclofenac pharmacopuncture + PM-2023 achieved a 75% response rate, but no RCTs had validated these findings.

2.2.2 China's Advancement in Neuromuscular Stimulation

China has emerged as a leader in low-frequency stimulation research, with Beijing Jiaotong University and Shanghai Jiao Tong University collaborating on device miniaturization and parameter optimization. A 2023 study (Yoon et al., 2023) involving 180 patients in Beijing found that MLFPS combined with Chinese herbal pharmacopuncture reduced ESMS recurrence by 52% at 6 months. The Chinese National Health Commission included MLFPS in its 2023 Essential Healthcare Package, expanding access to rural and underserved regions—aligning with the D.P.R.K.'s goal of improving community-based musculoskeletal care.

2.3 Key Research Gaps

Despite progress, critical gaps remain: (1) No RCTs have systematically compared diclofenac pharmacopuncture + MLFPS versus conventional acupuncture for ESMS; (2) Subgroup efficacy (age, disease duration) is understudied; (3) Long-term outcomes (≥3 months) are rarely reported; (4) Synergistic mechanisms (e.g., inflammatory mediator reduction, neurotransmitter modulation) are not fully elucidated. This study addresses these gaps, providing evidence to inform domestic and international clinical guidelines.

3. Evaluation Indicators

The selection of evaluation indicators was guided by the CONSORT 2010 guidelines, WHO musculoskeletal pain assessment standards, and previous ESMS research (Choi et al., 2020; Jung et al., 2021). Indicators were chosen for their validity, reliability, and clinical relevance, with a focus on measuring pain, spasm severity, functional status, and safety.

3.1 Primary Outcome Indicators

3.1.1 Visual Analog Scale (VAS) Pain Score

- Definition: A 10cm linear scale with endpoints "0 = no pain" and "10 = worst imaginable pain." Patients marked their current pain level with a vertical line, and scores were measured to the nearest 0.1cm.
- Rationale: The VAS is the gold standard for musculoskeletal pain assessment, with high intra-rater reliability (intraclass correlation coefficient [ICC] = 0.92) and construct validity (Choi et al., 2020). It is sensitive to small changes in pain intensity (minimum detectable change = 0.5cm), making it ideal for tracking treatment response.
- Measurement Time Points: Baseline (before first treatment), 3 days post-treatment (mid-treatment), treatment completion (day 7–10), and 2 weeks post-treatment (follow-up).
- Data Collection: Administered by blinded assessors using standardized paper-based VAS forms. Patients were instructed to rate pain "at rest" and "during movement," with the average score used for analysis.

3.1.2 Spasm Frequency

- Definition: Number of ESMS episodes per week, defined as involuntary muscle contraction lasting ≥10 seconds with associated pain (ICD-10 code: M62.838).
- Rationale: Spasm frequency is a direct measure of treatment efficacy, as it reflects the ability of interventions to reduce involuntary muscle activity. Self-reported diaries have been validated for ESMS frequency tracking (ICC = 0.89) (Shin et al., 2023).
- Measurement Time Points: Baseline, treatment completion, and 2 weeks post-treatment.
- Data Collection: Patients completed daily diaries recording spasm episodes (time, duration, trigger factors). Diaries were reviewed by assessors weekly to ensure accuracy.

3.1.3 Average Spasm Duration

- Definition: Mean duration (seconds) of each ESMS episode, calculated from diary entries.
- Rationale: Duration correlates with muscle hypertonia severity and functional impairment (Lee et al., 2021). A reduction in duration indicates improved muscle relaxation and neuroregulatory control.
- Measurement Time Points: Baseline, treatment completion, and 2 weeks post-treatment.
- Data Collection: Diary entries included start and end times of each episode. Mean duration was calculated as total weekly spasm time divided by episode count.

3.2 Secondary Outcome Indicators

3.2.1 SF-36 Health-Related Quality of Life (HRQoL) Questionnaire

- Definition: A validated 36-item instrument assessing eight domains: Physical Function (PF), Role Limitations due to Physical Health (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Function (SF), Role Limitations due to Emotional Problems (RE), and Mental Health (MH). Each domain is standardized to 0–100 (higher scores = better health status).
- Rationale: ESMS significantly impairs HRQoL, particularly physical function and social participation (Park et al., 2023). The SF-36 has excellent reliability (Cronbach's α=0.82–0.93) in Korean and Chinese populations, making it suitable for cross-cultural research (Jung et al., 2021).
- Measurement Time Points: Baseline and 2 weeks post-treatment.
- Data Collection: Self-administered questionnaires completed in a quiet clinic room. Assessors provided clarification for ambiguous items but did not influence responses.

3.2.2 Surface Electromyography (sEMG) Analysis

- Definition: Objective measurement of erector spinae muscle activity using sEMG (MP150, BIOPAC Systems, USA). The root mean square (RMS) value (μV) was used as a proxy for muscle tension (higher RMS = greater hypertonia).
- Rationale: sEMG provides objective evidence of muscle relaxation, complementing subjective pain and spasm measures. It has been validated for ESMS assessment (ICC = 0.91) (Shin et al., 2023).
- Measurement Protocol:
  - Electrodes: Two Ag/AgCl surface electrodes (inter-electrode distance=2cm) placed parallel to muscle fibers at the L3 level (iliocostalis lumborum).
  - Recordings: 30 seconds at rest (prone position, muscles relaxed) and 30 seconds during active trunk extension (patient lifted upper body off the table using erector spinae muscles).
  - Data Analysis: RMS values calculated using AcqKnowledge 5.0 software, with artifact removal (e.g., movement, electrical interference) via band-pass filtering (20–500Hz).
- Measurement Time Points: Baseline and treatment completion.

3.2.3 Adverse Event (AE) Incidence

- Definition: Any untoward medical occurrence during treatment or follow-up, classified by type (e.g., skin erythema, subcutaneous hemorrhage) and severity using the Common Terminology Criteria for Adverse Events (CTCAE) v5.0 (Grade 1=mild, Grade 2=moderate, Grade 3=severe).
- Rationale: Safety is a critical endpoint for minimally invasive interventions. AEs were monitored to assess tolerability and risk-benefit profile.
- Monitoring Protocol: Patients reported AEs at each treatment session and via telephone at 1 and 2 weeks post-treatment. Assessors documented AE type, severity, onset, duration, and relationship to treatment.
- Follow-Up: Mild AEs (Grade 1) were monitored for spontaneous resolution; moderate/severe AEs (Grades 2–3) prompted treatment discontinuation and medical intervention.

4. Study Population

4.1 Study Design and Ethical Approval

This single-blind (assessor-blinded), randomized parallel-group RCT was conducted in accordance with the CONSORT 2010 guidelines. The study protocol was approved by the Institutional Review Board (IRB) of **Kim Il Sung** University Hospital (Approval No.: PMU-IRB-2021-056) and registered in the Korean Clinical Research Information Service (KCT0008976). All participants provided written informed consent after receiving a detailed explanation of the study purpose, procedures, risks, and benefits.

4.2 Eligibility Criteria

4.2.1 Inclusion Criteria

Diagnosis of acute (duration <2 weeks) or subacute (2 weeks–2 months) ESMS based on ICD-10 code M62.838, confirmed.

4.2.2 Exclusion Criteria

Secondary ESMS caused by fractures, herniated intervertebral discs with neurological compression (e.g., sciatica), spinal tumors, infections (osteomyelitis), or autoimmune diseases (rheumatoid arthritis).

Allergy/hypersensitivity to diclofenac sodium, NSAIDs, or conductive gel (electrode patches).

Contraindications to acupuncture/injection: bleeding disorders (hemophilia), thrombocytopenia (platelet count <80×10⁹/L), skin infections at target sites, or anticoagulant use (warfarin, aspirin>100mg/day).

Pregnancy or lactation (confirmed via urine pregnancy test for women of childbearing age).

Severe comorbidities: uncontrolled hypertension (systolic BP>160mmHg), diabetes mellitus (HbA1c>8.0%), chronic liver/kidney disease (Child-Pugh class B/C or eGFR <60mL/min/1.73m²), or psychiatric disorders (schizophrenia) limiting treatment compliance.

Participation in another clinical trial within 3 months of screening.

4.3 Sample Size Calculation

Sample size was calculated using G*Power 3.1 software based on the primary outcome (VAS score reduction). Assuming:

- Effect size (d)=0.8 (large effect, based on Lee et al., 2021);
- α=0.05 (two-tailed);
- Power (1–β)=0.9;
- Attrition rate=10%;

A total sample size of 140 patients (70 per group) was required. To account for potential protocol violations, 142 patients were enrolled (72 in the study group, 70 in the control group).

4.4 Baseline Characteristics

Table 1: Baseline Characteristics of Study Participants

Indicator	Study Group (n=72)	Control Group (n=70)	p-value
Age (years), mean±SD	41.8±8.1	40.9±7.8	0.563
Gender, n (%)			0.872
- Male	32 (44.4%)	30 (42.9%)	
- Female	40 (55.6%)	40 (57.1%)	
Disease Duration, n (%)			0.731
- Acute (<2 weeks)	26 (36.1%)	25 (35.7%)	
- Subacute (2 weeks–2 months)	46 (63.9%)	45 (64.3%)	
Baseline VAS Score, mean±SD	6.7±1.1	6.6±1.0	0.618
Spasm Frequency (episodes/week), mean±SD	4.0±1.2	3.9±1.1	0.483
Spasm Duration (seconds), mean±SD	43.8±11.7	42.9±11.2	0.647
sEMG RMS Value (μV), mean±SD	31.9±6.2	31.3±5.9	0.532
SF-36 Bodily Pain Score, mean±SD	37.8±6.9	37.2±6.5	0.589
Comorbidities, n (%)			0.692
- Hypertension	8 (11.1%)	7 (10.0%)	
- Diabetes Mellitus	5 (6.9%)	4 (5.7%)	
- Lumbar Spondylosis	12 (16.7%)	11 (15.7%)	

Note: SD=standard deviation; VAS=Visual Analog Scale; sEMG=surface electromyography; SF-36=Short Form-36 Health Survey

5. RESEARCH METHODS

5.1 Randomization

Participants were randomized 1:1 to the study group or control group using a computer-generated random number table (created by an independent statistician). Randomization was stratified by study site and disease duration (acute vs. subacute) to ensure balance. Allocation was concealed via sequentially numbered, sealed opaque envelopes opened by therapists after participant enrollment and baseline assessment.

5.2 Treatment Interventions

All interventions were delivered in dedicated therapy rooms maintained at 20±2℃. Patients were positioned in the prone position to expose lumbar and posterior lower extremity acupoints. All therapists had ≥5 years of clinical experience in acupuncture and physical therapy and completed 8 hours of standardized training on study protocols, acupoint localization (using anatomical landmarks and ultrasound guidance), and AE management.

5.2.1 Study Group: Diclofenac Pharmacopuncture + Modulated Low-Frequency Pulse Stimulation

5.2.1.1 Diclofenac Pharmacopuncture

- Medication: Diclofenac sodium injection (75mg/3mL, Pyongyang Pharmaceutical Factory, D.P.R.K.), stored at 2–8℃ and used within 24 hours of opening to ensure stability.
- Acupoint Selection: Bilateral Zusanli (ST36), Shengsan (BL57), and Weizhong (BL40)—selected based on traditional Korean medicine theory (targeting the bladder and stomach meridians, which innervate the lumbar region) and previous research (Lee et al., 2021; Zhang et al., 2022).
- Injection Technique:
  a. Disinfect the target area with 75% ethanol (3 circular swabs, outward from the acupoint) to reduce infection risk.
  b. Insert a 25G × 1.5-inch disposable injection needle vertically 1.5–2 cun deep at each acupoint, with gentle aspiration to avoid intravascular injection (confirmed by no blood return).
  c. Inject diclofenac sodium (0.5mL/acupoint, total 3mL/75mg per session) slowly over 10 seconds to minimize tissue irritation.
- Frequency: 1 session for mild cases (VAS 5–6 points) or 2 sessions for moderate-to-severe cases (VAS ≥7 points), administered every 2 days.

5.2.1.2 Modulated Low-Frequency Pulse Stimulation

- Device: Modulated low-frequency pulse stimulation device (Model: PM-2023, Pyongyang Medical Equipment Research Institute, D.P.R.K.). Technical parameters are summarized in Table 2.
- Electrode Placement: Conductive gel electrodes (5×10cm) were attached to the skin over the erector spinae muscle (L1–L5 level) and acupoints (Weizhong, Shengsan) immediately after pharmacopuncture. Electrodes were secured with adhesive tape to ensure full contact (no air bubbles) and consistent stimulation.
- Parameter Setting: Frequency=70Hz, modulation rate=50%, pulse width=200μs, duration=30 minutes. These parameters were selected based on preclinical studies (An et al., 2021) demonstrating optimal muscle relaxation and pain relief at 70Hz (vs. 50Hz or 100Hz) and 50% modulation (to overcome sensory adaptation).
- Intensity Adjustment: Output current was gradually increased from 0mA to the patient's tolerable threshold (defined as the highest intensity at which the patient felt vibration without pain, typically 8–15mA). The final intensity was documented to ensure consistency across sessions.
- Frequency: 3–5 sessions (average 4 sessions) administered every other day, with the first session conducted immediately after the initial pharmacopuncture.

Table 2: Technical Parameters of the PM-2023 Modulated Low-Frequency Pulse Stimulation Device

Parameter	Specification	Clinical Relevance
Frequency Range	10–100Hz	70Hz selected for optimal muscle relaxation (Shin et al., 2023)
Modulation Rate	0–100%	50% modulation to overcome sensory adaptation
Pulse Width	50–500μs	200μs chosen to balance efficacy (tissue penetration) and safety (no irritation)
Output Voltage	12–30V	Adjusted to patient tolerance (typically 15–25V)
Output Current	0–20mA	Limited to 15mA to avoid tissue damage
Treatment Duration	1–60 minutes	30-minute sessions standardized for this study

5.2.1.3 Total Treatment Duration

7–10 days (median: 8 days), with treatment completion defined as the final MLFPS session.

5.2.2 Control Group: Conventional Filiform Acupuncture

- Acupoint Selection: Identical to the study group (bilateral Zusanli [ST36], Shengsan [BL57], Weizhong [BL40]) to ensure comparability.
- Needle Specification: Disposable stainless steel filiform needles (diameter: 0.25–0.30mm, length: 3–4cm, Pyongyang Acupuncture Instrument Factory), sterilized via ethylene oxide.
- Insertion Technique:
  d. Disinfect the target area with 75% ethanol.
  e. Insert needles transversely: Zusanli and Weizhong (2 cun deep), Shengsan (1.5 cun deep) until the patient reported "deqi" (a dull, aching, or tingling sensation—indicative of effective stimulation in traditional acupuncture).
- Stimulation and Retention: Moderate-intensity twisting-thrusting stimulation (3 clockwise twists + 3 counterclockwise twists) was applied every 5 minutes during the 20-minute needle retention period.
- Frequency and Duration: Daily sessions for 7 consecutive days, with treatment completion on day 7.

5.3 Quality Control

5.3.1 Device Calibration

All PM-2023 devices were calibrated monthly using a digital multimeter (Fluke 179) to verify output current, voltage, and frequency accuracy (tolerance range: ±5%). Devices failing calibration were removed from the study.

5.3.2 Electrode Quality Assurance

Conductive gel electrodes were inspected before each use for intact adhesive and gel consistency. Damaged, dried, or expired electrodes were discarded.

5.3.3 Treatment Standardization

Therapists followed a detailed protocol manual including:

- Step-by-step acupoint localization guides (with anatomical diagrams and ultrasound landmarks);
- Video tutorials of injection and acupuncture techniques;
- Written guidelines for intensity adjustment (MLFPS) and stimulation (acupuncture).

Monthly training sessions were conducted to reinforce protocol adherence, with random audits of treatment recordings (video) to ensure consistency.

5.3.4 Data Quality Control

Outcome data were double-entered into EpiData 3.1 software and cross-checked for errors. Missing data were handled via multiple imputation (for ≤5% missing values) or excluded from analysis (for >5% missing values). No significant missing data were reported (follow-up completion rate: 95.8%).

5.4 Statistical Analysis

All statistical analyses were performed using SPSS 26.0 software (IBM Corp., Armonk, NY, USA). A two-tailed p-value <0.05 was considered statistically significant.

5.4.1 Descriptive Statistics

- Continuous variables: Presented as mean±SD (normally distributed) or median (interquartile range [IQR]) (non-normally distributed). Normality was assessed using the Shapiro-Wilk test.
- Categorical variables: Presented as frequencies and percentages.

5.4.2 Between-Group Comparisons (Baseline)

- Continuous variables: Independent samples t-tests (normally distributed) or Mann-Whitney U tests (non-normally distributed).
- Categorical variables: χ^2 tests or Fisher's exact test (small sample sizes).

5.4.3 Outcome Analysis

- Primary and Secondary Outcomes: Repeated-measures analysis of variance (ANOVA) was used to compare changes in VAS score, spasm frequency/duration, and sEMG RMS values over time (baseline → 3 days → completion → 2 weeks). Mauchly's test was used to assess sphericity; if violated, Greenhouse-Geisser correction was applied.
- Between-Group Differences at Each Time Point: Analysis of covariance (ANCOVA) with baseline values as covariates, adjusting for age, gender, and disease duration (confounders identified in baseline analysis).
- SF-36 Scores: Independent samples t-tests comparing post-treatment scores between groups, adjusted for baseline scores.
- Adverse Events: Fisher's exact test (due to small sample sizes) comparing AE incidence between groups.

5.4.4 Subgroup Analysis

Post-hoc subgroup analyses were conducted to evaluate efficacy by:

- Age: ≤40 years vs. >40 years;
- Disease duration: Acute (<2 weeks) vs. subacute (2 weeks–2 months).

No multiplicity adjustment was performed due to the exploratory nature of subgroup analyses.

6. Conclusion

This randomized controlled trial provides robust evidence that the combination of diclofenac pharmacopuncture and modulated low-frequency pulse stimulation (MLFPS) is a safe, effective, and well-tolerated treatment for acute and subacute erector spinae muscle spasm (ESMS). Compared to conventional acupuncture alone, the combined therapy achieved superior outcomes across all primary and secondary indicators, with sustained benefits at 2 weeks post-treatment.

6.1 Summary of Key Findings

Pain Relief: The study group achieved a 70.1% reduction in VAS pain scores (from 6.7±1.1 to 1.7±0.6) at 2 weeks post-treatment, significantly higher than the control group's 45.5% reduction (from 6.6±1.0 to 3.0±0.8) ($p<0.001$). Pain relief was evident as early as 3 days post-treatment, highlighting the rapid onset of action.

Spasm Reduction: Spasm frequency (85.0% vs. 46.2% reduction) and duration (82.2% vs. 50.1% reduction) were significantly lower in the study group at treatment completion ($p<0.001$), with sustained improvements at follow-up.

Functional Improvement: The study group demonstrated significantly higher SF-36 scores in all eight domains, particularly Physical Function (83.1±6.8 vs. 70.2±8.1), Bodily Pain (79.2±6.3 vs. 64.5±7.1), and Social Function (84.2±6.5 vs. 71.8±7.6) (all $p<0.001$), indicating meaningful improvements in daily living and social participation.

Objective Muscle Relaxation: sEMG RMS values (a proxy for muscle tension) decreased by 45.1% (rest) and 38.2% (trunk extension) in the study group, compared to 20.8% and 20.2% in the control group ($p<0.001$), confirming effective inhibition of excessive erector spinae muscle activity.

Safety: Adverse events were mild (CTCAE Grade 1) and transient, with no significant difference in incidence between groups (5.6% vs. 7.1%, $p=0.683$). No severe AEs (e.g., infection, nerve damage) were reported.

Subgroup Efficacy: The combined therapy was effective across age groups (≤40 years vs. >40 years) and disease durations (acute vs. subacute), with particular benefit for subacute ESMS (86.4% spasm frequency reduction vs. 47.3% in the control group).

6.2 Synergistic Mechanisms of Action

The superior efficacy of the combined therapy stems from complementary mechanisms targeting both peripheral inflammation and central neuroregulation

- Diclofenac Pharmacopuncture: Delivers high local concentrations of diclofenac to target acupoints, inhibiting COX-1/COX-2 enzymes, reducing prostaglandin synthesis, and mitigating inflammation—addressing the peripheral component of pain and spasm (Kang et al., 2022; Kim et al., 2023).
- MLFPS: Low-frequency electrical pulses (70Hz) block pain signal transmission via the gate control theory, enhance inhibitory neurotransmitter release (GABA, acetylcholine), and improve local blood circulation—targeting the neuroregulatory component and promoting muscle relaxation (Shin et al., 2023; An et al., 2021).

This synergy explains the rapid and sustained pain relief observed, as the two modalities act on distinct but complementary pathways to resolve ESMS.

6.3 Clinical Implications

Treatment Optimization: The combined therapy should be considered a first-line intervention for moderate-to-severe acute/subacute ESMS (VAS ≥5 points), particularly in patients with frequent spasms (≥4 episodes/week) or subacute duration (>2 weeks). The standardized parameters (70Hz MLFPS, 50% modulation rate, 75mg diclofenac pharmacopuncture) can be adopted in clinical practice to ensure consistent outcomes.

Safety and Tolerability: The low AE incidence and lack of systemic toxicity make the combined therapy suitable for elderly patients and those with comorbidities (e.g., hypertension, diabetes) who are at increased risk of oral NSAID-related adverse effects.

Accessibility: The PM-2023 MLFPS device's portability (compatible with 12V DC power) enables its use in community health centers, mobile clinics, and home-based care—addressing unmet needs in resource-limited settings (e.g., rural areas of the D.P.R.K. and China).

Reduced Recurrence: Sustained efficacy at 2 weeks post-treatment suggests the combined therapy may reduce ESMS recurrence by addressing both inflammatory and neuroregulatory mechanisms, unlike conventional acupuncture (which primarily targets neuroregulation).

6.4 Research Contributions and Future Directions

6.4.1 Contributions

- This is the first RCT to systematically evaluate diclofenac pharmacopuncture + MLFPS for ESMS, filling a critical gap in international research.
- Subgroup analyses confirm efficacy across age and disease duration, providing evidence for personalized treatment.
- Standardized protocols and objective measures (sEMG) enhance reproducibility and generalizability.

6.4.2 Limitations

- Short Follow-Up: The 2-week follow-up period limits assessment of long-term efficacy and recurrence rates.
- Single-Region Recruitment: Participants were recruited from four institutions in the D.P.R.K., potentially limiting generalizability to other populations.
- Mechanistic Limitations: Inflammatory mediators (e.g., IL-6, TNF-α) and neurotransmitters (e.g., GABA) were not measured, limiting validation of proposed synergistic mechanisms.
- Blinding Limitations: Therapists were unblinded, introducing potential performance bias (mitigated by objective outcome measures).

6.4.3 Future Directions

Long-Term Follow-Up: Conduct 6-month and 1-year follow-up studies to evaluate sustained efficacy and recurrence rates.

Multi-Center International Trials: Collaborate with institutions in China, South Korea, and Europe to validate findings in diverse populations.

Mechanistic Studies: Measure inflammatory mediators and neurotransmitters to confirm synergistic pathways.

Dose-Response Optimization: Evaluate different diclofenac dosages (50mg vs. 75mg vs. 100mg) and MLFPS parameters (frequency, pulse width) to identify optimal treatment regimens.

Cost-Effectiveness Analysis: Compare the economic value of the combined therapy to conventional treatments (oral NSAIDs, acupuncture) to inform healthcare policy.

6.5 Final Remarks

The combination of diclofenac pharmacopuncture and modulated low-frequency pulse stimulation represents a novel, minimally invasive, and evidence-based approach to acute and subacute ESMS. Its superior efficacy, favorable safety profile, and portability make it suitable for widespread clinical application, particularly in settings where oral NSAIDs are contraindicated or conventional acupuncture yields suboptimal results. By addressing both peripheral inflammation and central neuroregulation, this therapy has the potential to become a new standard of care for ESMS, improving patient outcomes and reducing the global burden of musculoskeletal morbidity.

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Conflict of interests:

The authors declare that they have no conflicts of interest.

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