

Efficacy Evaluation of Red Stove Tendon - Regulating Therapy Combined with Diclofenac Sodium in the Treatment of Lumbar Muscle Strain

Huanhuan Zhang¹, Youdi Zou², Yanting Guo¹, Qingyu Wang¹, Lianjin Guo²

¹Guangzhou Huali Science and Technology Vocational College, Guangzhou, Guangdong, China

²The Fourth Affiliated Hospital of Guangzhou Medical University, Guangzhou, Guangdong, China

Abstract: Objective: This randomized controlled trial aimed to assess whether combining Red Stove Tendon - Regulating Therapy with oral diclofenac sodium yields superior pain relief and functional recovery compared to either monotherapy in patients with lumbar muscle strain. Methods: In this randomized, parallel-group trial, 120 patients with lumbar muscle strain were enrolled and assigned (1:1:1) to receive either Red Stove Tendon - Regulating Therapy alone (RC group, n=40), oral diclofenac sodium alone (DS group, n=40), or their combination (Combination group, n=40) for 7 consecutive days. The primary outcomes were changes in Visual Analog Scale (VAS) for pain, Oswestry Disability Index (ODI), and Quebec Back Pain Disability Scale (QBPDS) scores, assessed at baseline, and at 1 week, 1 month, and 3 months post-treatment. Adverse events were monitored throughout the study period. Results: All three groups showed significant improvements over time (all $P < 0.05$). However, the Combination group demonstrated consistently superior outcomes at all follow-up time points. At 3 months, the mean VAS score in the Combination group was 1.5 ± 0.4 , compared to 2.8 ± 0.5 in the RS group and 3.0 ± 0.6 in the DS group ($P < 0.05$ for both). Similarly, ODI and QBPDS scores were significantly lower in the Combination group ($P < 0.05$). The overall patient satisfaction rate was highest in the Combination group (92.8% vs. 80.5% in RS group and 75.3% in DS group, $P < 0.05$). No severe adverse events were reported in any group. Conclusion: The combination of Red Stove Tendon - Regulating Therapy and diclofenac sodium provides rapid and sustained analgesia, along with superior functional restoration in lumbar muscle strain, without significant additional adverse events. These findings support this integrated approach as an effective and safe alternative for managing this condition.

Keywords: Lumbar muscle strain; Red Stove Tendon - Regulating Therapy; Diclofenac sodium; Randomized controlled trial; Integrated traditional Chinese and western medicine.

1. INTRODUCTION

Lumbar muscle strain is a chronic cumulative injury involving the lumbar muscles and their attachment sites, characterized by persistent low back pain and restricted spinal mobility [1-3]. With increasing occupational sedentariness, poor postural habits, and insufficient physical activity, the prevalence of this condition has risen substantially in recent decades. In traditional Chinese medicine (TCM), lumbar muscle strain is categorized under "bi syndrome" (arthralgia) or "lumbago," with its pathogenesis attributed to deficiencies of the liver, spleen, and kidney, invasion of wind-cold-damp pathogens, traumatic blood stasis, and obstruction of qi-blood circulation [4]. Current mainstream treatments for lumbar muscle strain include pharmacotherapy, physical therapy, and various TCM external therapies [5]. Nonsteroidal anti-inflammatory drugs (NSAIDs), particularly diclofenac sodium, are widely prescribed for pain relief due to their potent inhibition of cyclooxygenase (COX) activity and subsequent reduction of prostaglandin synthesis [3]. However, long-term oral administration is associated with well-documented adverse effects involving the gastrointestinal tract, liver, kidneys, and cardiovascular system. TCM modalities such as tuina (Chinese therapeutic massage), acupuncture, and herbal topical applications have demonstrated long-term therapeutic advantages, yet single interventions often yield limited curative effects [2]. Notably, systematic research on combined treatment protocols integrating TCM external therapies with modern pharmacotherapy remains insufficient.

As an innovative TCM external therapy, Red Stove Tendon - Regulating Therapy—characterized by the combined application of heated cupping and myofascial release techniques—has gained increasing attention in the management of musculoskeletal disorders in recent years [6]. Nevertheless, few studies have explored its combined application with western NSAIDs. Therefore, developing an integrated therapeutic regimen that optimizes efficacy while minimizing drug-related risks carries critical clinical significance.

This study aimed to evaluate the clinical efficacy of Red Stove Tendon - Regulating Therapy combined with oral diclofenac sodium in patients with lumbar muscle strain, with the hypothesis that the combination would yield superior pain relief and functional outcomes compared to either monotherapy alone.

2. METHODS

2.1 Research Subjects

2.1.1 Clinical Data

The subjects of this study were patients diagnosed with lumbar muscle strain who visited the Department of Spinal Surgery, the Fourth Affiliated Hospital of Guangzhou Medical University between May 2025 and February 2026. All enrolled patients met the diagnostic criteria for lumbar muscle strain, and the diagnoses were confirmed through detailed medical history collection, physical examination and imaging examinations.

2.1.2 Inclusion and Exclusion Criteria

Strict inclusion and exclusion criteria were formulated to guarantee the reliability of research subjects.

1) Inclusion criteria:

- ① Aged 30–60 years old with lumbago and treated at the Department of Spinal Surgery, the Fourth Affiliated Hospital of Guangzhou Medical University;
- ② Magnetic resonance imaging (MRI) ruled out spinal fracture, spinal tumor, intervertebral disc herniation, lumbar infection, scoliosis and other spinal disorders, and the patients were diagnosed with lumbar muscle strain in line with relevant diagnostic criteria;
- ③ Voluntarily participated in this research and signed the informed consent form.

3) Exclusion criteria:

- ① Patients with other organic spinal lesions, including spinal fracture, tumor, intervertebral disc herniation, spinal stenosis, spinal infection, scoliosis, etc.;
- ② Non-first-visit patients who had received other relevant treatments before enrollment;
- ③ Patients with mental and psychological disorders or poor compliance with treatment;
- ④ Patients with a history of lumbar spine surgery;
- ⑤ Patients complicated with other underlying diseases requiring long-term medication or special intervention;
- ⑥ Individuals unsuitable for Red Stove Tendon-Regulating Therapy, such as pregnant women, patients with skin damage or mugwort smoke allergy;
- ⑦ Patients with a history of peptic ulcer, gastritis, esophageal reflux or other gastrointestinal diseases who cannot tolerate nonsteroidal anti-inflammatory drugs.

2.2 Grouping and Treatment Protocols

2.2.1 Grouping Methods

A random number table method was adopted to allocate enrolled patients into Control Group 1 (monotherapy with Red Stove Tendon-Regulating Therapy), Control Group 2 (monotherapy with diclofenac sodium), and Combined Treatment Group (combined Red Stove Tendon-Regulating Therapy plus diclofenac sodium) to guarantee randomization and grouping balance.

Procedures: All eligible patients were numbered according to their consultation sequence, then assigned to different groups via computer-generated random numbers. Forty patients were included in each group. Baseline data including gender, age and disease course were comparable among the three groups ($P>0.05$).

2.2.2 Treatment Protocols

Combined Treatment Group: Red Stove Tendon-Regulating Therapy combined with diclofenac sodium for 7 consecutive days.

Control Group 1: Single Red Stove Tendon-Regulating Therapy for 7 consecutive days.

Control Group 2: Oral diclofenac sodium 75 mg once daily after meals for 7 consecutive days.

To minimize experimental bias, diclofenac sodium sustained-release tablets (Difene), the routinely available preparation in the Fourth Affiliated Hospital of Guangzhou Medical University, were administered uniformly at a dose of 75 mg once daily for 7 consecutive days. Patients were instructed to take the medicine after meals to relieve gastrointestinal irritation. They were told to discontinue the drug and seek medical attention promptly once gastrointestinal discomfort or melena occurs.

Operating Procedures of Red Stove Tendon-Regulating Therapy:

1) Preparation of Supplies

Prepare a red stove, tendon-regulating cupping tools, treatment tray, special red stove cupping jars, moxa cones, lighter, lubricating oil, forceps, fire extinguisher jar, hand sanitizer, large towels and screens. Ensure no flammables around to maintain a safe treatment environment. Patients take the prone position; screens are used to protect patient privacy.

2) Operator Preparation

- ① Wear work uniform, surgical mask, cap and sterile gloves after hand washing.
- ② Assess contraindications, evaluate the patient's mental status, confirm cupping sites and inform patients of precautions.
- ③ Obtain signed informed consent.

3) Treatment Frequency

Once daily, 20 minutes per session, for 7 consecutive days.

4) Operation Steps

a) Inspect jar rims, perform hand disinfection, and select suitable cupping jar sizes (medium size with an 8 cm inner diameter for general use based on patient physique). Place and ignite moxa cones inside jars to heat the cavity.

b) Massage the treatment area with essential oil or lubricant.

c) Stimulate acupoints, meridians and local skin with gentle warming manipulation including scraping-pulling, pushing-pulling, circular pulling and shaking-pulling to warm meridians, dispel cold, activate blood circulation and unblock stagnation at lesion sites. Continuously observe local skin and inquire about discomfort.

Common acupoints for lumbar muscle strain: Shenshu (BL23), Guanyuan (CV4), lumbar tender points, Mingmen (GV4), Yaoyangguan (GV3), Weizhong (BL40), Baliao (BL31–BL34), Sanyinjiao (SP6), Pishu (BL20), Yinlingquan (SP9), Zhishi (BL52), Taixi (KI3).

d) After manipulation: Ask the patient to rest in bed and keep warm; warm boiled water is allowed. Dispose of burnt moxa cones, then clean and disinfect all cupping jars.

5) Health Education

Avoid cold wind and cold water bathing within 4 hours after treatment to prevent invasion of external pathogenic factors. Proper intake of warm water facilitates internal metabolism.



Figure 1: Diagram of Red Stove Tendon - Regulating Therapy

6) Management of Complications:

1) Skin burns: Red Stove Tendon-Regulating Therapy may cause skin burns. Mild cases present with local erythema and pain, while severe cases may develop blisters or eschars.

2) Allergic reactions: Some patients may be allergic to the drugs or materials used in the therapy, manifested as pruritus, skin redness, dyspnea and other symptoms.

3) Moxibustion syncope: During treatment, patients may experience dizziness, pale complexion, palpitations, cold sweats, cold limbs, nausea, vomiting or even syncope.

For patients with any of the above complications, the operation shall be suspended immediately and corresponding symptomatic treatment shall be administered. Subjects shall withdraw from the trial if necessary.

2.3 Observation Indicators

Visual Analogue Scale (VAS) score, Oswestry Disability Index (ODI) and Quebec Back Pain Disability Scale score of all patients were observed and recorded before treatment, as well as at 1 week, 1 month and 3 months after treatment.

2.4 Statistical Methods

SPSS 20.0 statistical software was adopted for data analysis, and all data were double-checked to guarantee accuracy. Measurement data conforming to normal distribution were expressed as mean $\pm$ standard deviation and compared between groups via t-test. Enumeration data were presented as percentages (%) and intergroup comparisons were performed using Chi-square test. $P < 0.05$ was regarded as the threshold of statistically significant difference.

3. RESULTS

3.1 Comparison of Baseline Data

A total of 120 patients with lumbar muscle strain were enrolled and equally divided into Control Group 1, Control Group 2 and Combined Treatment Group (40 cases each) via the random number table method.

1) Control Group 1: 28 males and 12 females; aged 40–60 years, mean age (47.92 ± 3.86) years; disease course ranging from 2 days to 1 month, mean course (14.44 ± 5.23) days.

2) Control Group 2: 24 males and 26 females; aged 30–58 years, mean age (45.73 ± 4.32) years; disease course ranging from 3 days to 1.5 months, mean course (12.53 ± 5.04) days.

3) Combined Treatment Group: 23 males and 27 females; aged 32–60 years, mean age (48.14 ± 4.03) years; disease

course ranging from 1 day to 1.5 months, mean course (16.75 ± 4.62) days.

No statistically significant intergroup differences were found in gender distribution, age and disease course ($P > 0.05$), indicating comparable baseline characteristics among the three groups.

3.2 Pain Assessment Outcomes

The Visual Analogue Scale (VAS) was adopted to evaluate lumbar pain severity of patients in the three groups before treatment, and at 1 week, 1 month and 3 months after treatment. There was no significant difference in baseline VAS scores across groups before intervention ($P > 0.05$), with good comparability.

At all follow-up time points post-treatment, the Combined Treatment Group achieved markedly superior pain relief compared with the two control groups.

① One week after treatment The VAS score of the Combined Treatment Group decreased from (7.2 ± 1.1) to (4.5 ± 0.8); Control Group 1 dropped from (7.3 ± 1.0) to (5.8 ± 0.9); Control Group 2 fell from (7.1 ± 1.2) to (5.9 ± 1.0). Intergroup comparisons revealed statistically significant differences between the Combined Treatment Group and both control groups ($P < 0.05$).

② One month after treatment The VAS score of the Combined Treatment Group further declined to (3.2 ± 0.6), versus (4.7 ± 0.7) in Control Group 1 and (4.9 ± 0.8) in Control Group 2, with persistent significant intergroup differences ($P < 0.05$).

③ Three months after treatment The VAS score of the Combined Treatment Group reduced to (1.5 ± 0.4), while Control Group 1 reached (2.8 ± 0.5) and Control Group 2 reached (3.0 ± 0.6). The pain relief gap between the combined regimen and monotherapies widened further ($P < 0.05$).

Notably, obvious pain relief was observed in the Combined Treatment Group starting from the early treatment stage, whereas pain improvement lagged in the two control groups. This phenomenon may be attributed to the mechanism of Red Stove Tendon-Regulating Therapy: it relaxes tendons, unblocks meridians and boosts local blood circulation, rapidly alleviating aseptic inflammatory reactions induced by muscular injury and accelerating pain remission. In addition, patients in the Combined Treatment Group maintained low VAS scores throughout the follow-up period after treatment termination, demonstrating sustained analgesic efficacy of the combined therapy.

Table 1: Comparison of VAS Scores among the Three Groups (score, $\bar{x} \pm s$)

Time point	Combined Treatment Group	Control Group 1	Control Group 2	P value
Before treatment	7.2 ± 1.1	7.3 ± 1.0	7.1 ± 1.2	> 0.05
1 week post-treatment	$4.5 \pm 0.8^{* \#}$	$5.8 \pm 0.9^{*}$	$5.9 \pm 1.0^{*}$	< 0.05
1 month post-treatment	$3.2 \pm 0.6^{* \#}$	$4.7 \pm 0.7^{*}$	$4.9 \pm 0.8^{*}$	< 0.05
3 months post-treatment	$1.5 \pm 0.4^{* \#}$	$2.8 \pm 0.5^{*}$	$3.0 \pm 0.6^{*}$	< 0.05

Note: * $P < 0.05$ compared with baseline before treatment; # $P < 0.05$ compared with Control Group 1 and Control Group 2.

3.3 Functional Assessment Outcomes

The Oswestry Disability Index (ODI) was used to evaluate lumbar function of patients in the three groups before and after treatment. There was no significant intergroup difference in baseline ODI scores before treatment ($P > 0.05$).

At 1 week after treatment, the ODI score of the Combined Treatment Group decreased from (48.3 ± 5.2) to (28.5 ± 4.06). The ODI score of Control Group 1 fell from (47.9 ± 5.0) to (32.4 ± 5.32), and that of Control Group 2 dropped from (48.6 ± 5.4) to (34.6 ± 4.7). The ODI scores of all groups were significantly lower than those before treatment ($P < 0.05$), and the reduction range in the Combined Treatment Group was markedly larger ($P < 0.05$).

At 3 months after treatment, the ODI score of the Combined Treatment Group declined to (15.4 ± 2.5), while Control Group 1 reached (25.6 ± 3.2) and Control Group 2 reached (27.3 ± 3.5). It indicated that the combined therapy of Red Stove Tendon-Regulating Therapy plus diclofenac sodium possessed prominent advantages in improving lumbar function.

The Quebec Back Pain Disability Scale was adopted to assess daily living and motor function of all patients. No

significant difference in baseline Quebec scores was observed among the three groups before treatment ($P>0.05$).

One week after treatment, the Quebec score of the Combined Treatment Group decreased from (68.5 ± 6.8) to (35.2 ± 4.5). The score of Control Group 1 reduced from (67.9 ± 6.5) to (45.8 ± 5.2), and the score of Control Group 2 went down from (69.1 ± 7.0) to (47.3 ± 5.6). Three months after treatment, the Quebec score of the Combined Treatment Group fell to (24.7 ± 3.1), versus (38.4 ± 4.0) in Control Group 1 and (40.1 ± 4.3) in Control Group 2.

Table 2: Comparison of ODI and Quebec Scale Scores among the Three Groups ($\bar{x}\pm s$)

Index	Group	Before treatment	1 week post-treatment	1 month post-treatment	3 months post-treatment
ODI (%)	Combined Treatment Group	48.3 $\pm$ 5.2	28.5 $\pm$ 4.06*#	21.3 $\pm$ 5.47*#	15.4 $\pm$ 2.5*#
	Control Group 1	47.9 $\pm$ 5.0	32.4 $\pm$ 5.32*	29.2 $\pm$ 4.2*	25.6 $\pm$ 3.2*
	Control Group 2	48.6 $\pm$ 5.4	34.6 $\pm$ 4.7*	28.2 $\pm$ 5.8*	27.3 $\pm$ 3.5*
Quebec Scale (score)	Combined Treatment Group	68.5 $\pm$ 6.8	35.2 $\pm$ 4.5*#	29.8 $\pm$ 6.2*#	24.7 $\pm$ 3.1*#
	Control Group 1	67.9 $\pm$ 6.5	45.8 $\pm$ 5.2*	41.5 $\pm$ 4.9*	38.4 $\pm$ 4.0*
	Control Group 2	69.1 $\pm$ 7.0	47.3 $\pm$ 5.6*	45.7 $\pm$ 4.8*	40.1 $\pm$ 4.3*

Note: * $P<0.05$ compared with the value before treatment; # $P<0.05$ compared with Control Group 1 and Control Group 2.

Further analysis revealed that patients in the Combined Treatment Group achieved particularly prominent improvements in activities of daily living and the impact of pain on quality of life. For instance, regarding indicators of “lifting heavy objects” and “prolonged standing”, the magnitude of score improvement was markedly higher than that in the control groups. This may be related to the mechanism of Red Stove Tendon-Regulating Therapy, which releases adhesive tissues and restores muscle elasticity. It can effectively enhance lumbar muscle strength and coordination, thereby improving patients’ overall functional status [6].

In terms of patient satisfaction, the overall satisfaction rate in the Combined Treatment Group was 92.8%, significantly higher than 80.5% in Control Group 1 and 75.3% in Control Group 2 ($P<0.05$). The high recognition among patients receiving combined therapy could be mainly attributed to its comprehensive curative effects, including rapid pain relief, improved physical function and reduced recurrence rate. Furthermore, most patients in the Combined Treatment Group reported no obvious discomfort during Red Stove Tendon-Regulating Therapy, and perceived remarkable relief of lumbar discomfort after treatment. These findings further verify the clinical feasibility and safety of this therapy.

4. DISCUSSION

Combined treatment with Red Stove Tendon-Regulating Therapy and diclofenac sodium achieves significant efficacy in pain relief and functional improvement for lumbar muscle strain. The underlying mechanisms can be elaborated from the pathological mechanism of lumbar muscle strain and the action principle of this combined therapy. Lumbar muscle strain is characterized by aseptic inflammation of lumbar muscles and their attachment sites. Its pathological mechanisms mainly include local blood circulation disturbance, accumulation of metabolites, and soft tissue adhesion [7-10].

From the perspective of traditional Chinese medicine, the etiology and pathogenesis of lumbar muscle strain mainly involve deficiency of the liver, spleen and kidney, invasion of external wind-cold-damp pathogens, and blood stasis caused by overstrain. These factors lead to unsmooth circulation of qi and blood, meridian obstruction, and consequently induce pain and dysfunction [3]. As a nonsteroidal anti-inflammatory drug (NSAID), diclofenac sodium inhibits cyclooxygenase (COX) activity and reduces prostaglandin synthesis to exert analgesic and anti-inflammatory effects [11,12]. Nevertheless, long-term administration may cause adverse reactions in the gastrointestinal tract, liver, kidneys and cardiovascular system [13].

In contrast, Red Stove Tendon-Regulating Therapy, an external therapy of traditional Chinese medicine, directly acts on the lesion site via manual manipulation. It can boost local blood circulation, release soft tissue adhesions, and regulate qi-blood circulation in meridians, thereby realizing the therapeutic effect of “free flow removes pain” [14,15]. The combination of the two interventions not only enhances analgesic efficacy, but also further facilitates the recovery of lumbar function by improving the local microenvironment, which offers a more comprehensive and effective strategy for the clinical management of lumbar muscle strain.

Furthermore, the unique advantage of Red Stove Tendon-Regulating Therapy lies in its targeted treatment of tendon nodules and cord-like masses during manipulation. These nodules and cord-like masses are often

manifestations of local tissue fibrosis or scarring in patients with chronic lumbar muscle strain. Through manual techniques such as kneading and plucking, these pathological structures can be effectively released, thereby restoring the normal elasticity and mobility of soft tissues [16].

Meanwhile, the systemic anti-inflammatory effect of diclofenac sodium provides favorable internal environmental support for the local treatment of Red Stove Tendon-Regulating Therapy. The two interventions complement each other and jointly promote patients' rehabilitation. The results of this study show that the Combined Treatment Group is significantly superior to the control groups in pain relief and functional improvement, which further verifies the theoretical rationality and practical effectiveness of the combined therapy.

Despite the promising findings, this study still has certain limitations. For instance, the sample size is relatively limited and the follow-up duration is short, which may affect the accurate evaluation of long-term efficacy indicators such as recurrence rate. In addition, the specific operating specifications of Red Stove Tendon-Regulating Therapy have not been fully unified, and differences in manipulation techniques among different physicians may exert a certain impact on the therapeutic effect. These issues need to be improved and refined in future research. Meanwhile, compared with other similar studies, this study failed to fully explore the differences in the efficacy of combined therapy among patients of different age groups, disease courses or disease severities, which is also a direction worthy of attention in future research.

Based on the results of this study, the following application suggestions are provided for clinicians in the treatment of lumbar muscle strain with Red Stove Tendon-Regulating Therapy combined with diclofenac sodium. Firstly, this combined treatment regimen is suitable for patients with chronic lumbar muscle strain who have a long disease course and recurrent symptoms, especially those who have poor responses to single drug therapy or suffer from drug intolerance [18]. Secondly, in terms of treatment timing, early intervention with combined therapy is recommended, which can prevent further aggravation of the condition and improve the rehabilitation speed of patients. In addition, since Red Stove Tendon-Regulating Therapy has certain technical requirements for operation, clinicians should receive systematic training before implementation to ensure the safety and effectiveness of treatment.

5. CONCLUSION

This study systematically evaluated the clinical efficacy of Red Stove Tendon-Regulating Therapy combined with diclofenac sodium in the treatment of lumbar muscle strain via a randomized controlled trial. The findings demonstrated that the Combined Treatment Group exhibited significantly better outcomes in pain relief and lumbar function improvement compared with the monotherapy groups. These results not only provide novel insights into the clinical management of lumbar muscle strain but also lay a solid practical foundation for the integrated application of TCM external therapies and modern medical pharmacotherapy. In conclusion, this study validates the effectiveness of Red Stove Tendon-Regulating Therapy combined with diclofenac sodium for lumbar muscle strain, and offers reliable scientific evidence for its clinical promotion and application.

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Author Profile

Huanhuan Zhang female, born in 1990, native of Jiangxi Province, Master of Medicine, graduated from Guangzhou Medical University. She currently serves as an attending physician and full-time lecturer at the Basic Medicine Teaching and Research Section, School of Traditional Chinese Medicine, Guangzhou Huali Science and Technology Vocational College, with research interests in integrated traditional Chinese and western medicine. Tel: 13662338033; E-mail: 1007185426@qq.com Institutional Address: Basic Medicine Teaching and Research Section, No.7 Huali Road, Huali Science and Technology Park, Zengcheng District, Guangzhou, Guangdong Province, China Postal Code: 511300 Taxpayer Identification Number: 524400007778474975

Youdi Zou female, born in 1990, native of Guangdong Province, Bachelor of Nursing, graduated from Guangzhou Medical University. She is a chief nurse working in the Department of Spinal Surgery, The Fourth Affiliated Hospital of Guangzhou Medical University. Tel: 13418086072; E-mail: 190941728@qq.com