Randomized Controlled Trial

The Efficacy of Ultrasound-Guided Thoracic Paravertebral Blocks Using a Novel Analgesic Regimen for Thoracic Herpes Zoster–Associated Pain: A Randomized Controlled Trial

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Disclaimer: This study was supported by the Research Project of Wuxi Huishan District People's Hospital (No. 2023YJKT003). The study was approved by the Ethics Committee of Huishan District People's Hospital of Wuxi City (Approval No. HYLL20240103001) and registered at the Chinese Clinical Trial Registry (ChiCTR2400082392).

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Article received: 06-08-2025
Revised article received: 08-25-2025
Accepted for publication: 09-03-2025

Free full article: www.painphysicianjournal.com

Background: The main symptom of herpes zoster (HZ) is pain. While numerous antiviral agents, administered either orally or intravenously, have been recommended for treating this symptom in clinical practice, the optimal strategy for preventing HZ-associated pain remains uncertain.

Objective: This study aimed to evaluate the efficiency and safety of a novel analgesic mixture containing parecoxib for treating thoracic HZ neuralgia through ultrasound (US)-guided paravertebral blockades.

Study Design: An open-label, prospective, randomized clinical trial.

Setting: A university hospital.

Methods: Sixty patients with thoracic HZ neuralgia receiving appropriate antiviral therapy and pregabalin treatment were randomly divided into 2 equally sized groups. Group C (the control group) received a conventional mixture (0.25% lidocaine + 1/4 betamethasone + 0.1% ropivacaine + saline, 15 mL volume). Group N received the experimental mixture (the above components + 1000 μg of methylcobalamin + 20 mg of parecoxib, 15 mL in volume). Under US-guidance, 15 mL of the assigned mixture was injected below the costotransverse ligament at the affected thoracic segment. The scores on the numeric rating scale (NRS) and Pittsburgh Sleep Quality Index (PSQI) were assessed at baseline and at 12 hours and then 7 days after treatment. Safety parameters (nausea, vomiting, constipation, injection site reactions, pneumothorax, local anesthetic toxicity, and respiratory depression) were monitored.

Results: Both groups showed significant reductions in their NRS scores and improvements to their sleep ($P < 0.001$). Compared to the control mixture, the novel drug combination was associated with superior NRS scores ($P < 0.001$) and significantly improved PSQI scores ($P < 0.001$) at 7 days after treatment. Side effects and complications (nausea, vomiting, constipation, injection site reactions, pneumothorax, local anesthetic toxicity, and respiratory depression) were not observed in either group of patients.

Limitations: The sample size of this study was relatively small. Study section and publication bias might have affected the general findings.

Conclusions: Compared to conventional treatment, US-guided paravertebral blocks that used the novel drug combination provided more sustained analgesia and greater sleep quality enhancement without additional safety concerns. This optimized formulation represents a promising therapeutic approach for treating thoracic HZ-associated neuralgia.

Key words: Herpes zoster–associated pain, postherpetic neuralgia, ultrasound-guided methods, thoracic paravertebral block, parecoxib, neuralgia, NRS, PSQI

Pain Physician 2026: 29:E19-E27

Herpes zoster–associated pain (ZAP) is a neuropathic condition following varicella-zoster virus reactivation (1). ZAP is acknowledged as a challenging clinical problem. According to the research on disease burden and economic evaluation of herpes zoster report in China, the number of new cases of herpes zoster (HZ) in China exceeded 15 million in 2023, with the total annual economic burden reaching CNY 86.9 billion across the entire population of the nation. Therefore, investigating therapeutic optimization strategies for ZAP has considerable clinical research value and scientific significance.

Following initial infection in chickens or in vaccination, the varicella-zoster virus establishes a lifetime latency in the sensory neurons of dorsal root ganglia (DRGs) (2). Decreased cell-mediated immunity permits viral reactivation, characterized by the retrograde axonal transport of replicating virions from ganglia to cutaneous sensory nerve endings, culminating in the pathognomonic dermatomal rash and pain syndrome termed HZ (3). This condition causes long-term pain in approximately 90% of people who have it (4). The clinical course of ZAP can be classified into 3 distinct phases in clinical practice: acute herpetic neuralgia (AHN), subacute herpetic neuralgia (SHN), and postherpetic neuralgia (PHN) (5). Prodromal pain refers to the neuropathic pain phase occurring between the onset of HZ and the emergence of a characteristic rash. AHN denotes acute neuroinflammatory pain that persists from the first appearance of the rash until cutaneous healing is complete (typically ≤ 30 days). SHN is a transitional phase characterized by dissociation between cutaneous healing and persistent neuropathic pain, occurring 30-120 days after the onset of the rash. PHN is defined as chronic neuropathic pain persisting > 90 days after the resolution of the lesions (6). This clinical syndrome is characterized by sustained burning pain, electric shock–like paroxysms, and allodynia and is frequently accompanied by hyperesthesia, sleep disturbances, and anxiety–depression comorbidities, resulting in impaired quality of life. As the most prevalent complication, persistent PHN pain may trigger autonomic dysfunction, social disability, and long-term health care burdens, representing a significant public health challenge (7).

Notably, long-term ZAP or PHN may persist during antiviral therapy, which is driven by persistent virus-induced neuroinflammation, activation of glial cells, glial activation, and neuroimmune dysregulation (8). Therefore, it is necessary to administer antiviral drugs in combination with other drugs for pathological neuropathic pain. These adjunctive therapies include antianxiety drugs, ion channel modulators, and neurotrophic agents (9). Current clinical guidelines worldwide recommend early implementation of multimodal analgesia for optimal pain management. Current management combines pharmacological (anticonvulsants, antidepressants, analgesics) and interventional approaches. Nonopioid analgesics are commonly employed to manage acute pain associated with HZ. However, they often prove to be ineffective (10). Nerve block therapy is the most widely utilized clinical intervention for managing such pain and effectively combines anti-inflammatory and analgesic properties to prevent peripheral nerve sensitization (11). To achieve this objective, appropriate antiviral medications, oral analgesics, and various nerve block techniques may be employed. Multimodal analgesia encompasses techniques such as nerve blocks (12), spinal cord stimulation (SCS) implantation (13), and radiofrequency techniques for spinal nerve roots or DRGs (14). Among these methods, the thoracic paravertebral block (TPVB), particularly of the ultrasound (US)-guided variety, has emerged as a cornerstone intervention for thoracic zoster-related pain because of its efficacy, safety, and technical simplicity (15). TPVB can alleviate ZAP and reduce the incidence of PHN (16). The outcomes of TPVBs depend on the blockade level, drug selection, drug concentration, and treatment frequency (17). The evidence supports the use of combined local anesthetic-corticosteroid formulations for acute pain management and PHN prevention (18). Therefore, the way to achieve optimal pain management is an important clinical issue currently facing ZAP.

In China, conventional TPVB mixtures usually include corticosteroids (compounds betamethasone/dexamethasone), local anesthetics, methylcobalamin, and normal saline. However, their short-term therapeutic effects often require repeated interventions or adjunctive therapies, such as spinal cord stimulation. Although orally or intravenously administered antiviral drugs have been included in evidence-based clinical guidelines, the gold-standard preventive strategy for HZ-associated neuropathic pain has not been definitively established in the therapeutic field. This study investigated an optimized drug combination by adding 20 mg parecoxib to evaluate its short-term efficacy in the management of thoracic ZAP. This novel formulation aims to enhance therapeutic outcomes while maintaining safety.

Methods

The study was conducted as a prospective, randomized clinical trial at Huishan District People's Hospital. All patients provided written informed consent for treatment while retaining the right to withdraw without prejudice at any stage.

Patients

Sixty-four patients aged 18–90 years with thoracic-segment ZAP who presented pain scores ≥ 6 on the Numerical Rating Scale (NRS) were enrolled in this study. Patients were recruited from the Pain Clinic of Wuxi People's Hospital and Huishan District People's Hospital in Wuxi City between February 2024 and February 2025. Four patients were excluded from the study, including 2 who declined participation and 2 who were lost to follow-up. Patients were able to communicate well and understand how to score their pain levels. Sixty patients were randomly classified in parallel into 2 groups via sealed envelopes (n = 30). A doctor who did not participate in the study created the random allocation sequence. The control group was injected with a conventional mixture of 0.25% lidocaine (20241033, Hubei Tianshen Pharmaceutical Co., Ltd.) + 1/4 betamethasone (1000138722, Organon GmbH [Switzerland] Hangzhou MSD Pharmaceutical Co., Ltd.) + 0.1% ropivacaine (EE2446, Zhejiang Xianju Pharmaceutical Co., Ltd.) + saline (25A9252, China Otsuka Pharmaceutical Co.), and the novel group was injected with the above components + 1000 μg methylcobalamin (N24111522, Chenxin Pharmaceutical Co., Ltd.) + 20 mg parecoxib (241104014, Emeishan Tonghui Pharmaceutical Co., Ltd.). The demographic data are shown in Table 1. The patients were studied according to the flow diagram (Fig. 1).

Patients who fulfilled any of the following criteria were excluded from participation:

1. contraindications to thoracic paravertebral block (patient refusal or anatomical constraints)
2. hypersensitivity to the study medications
3. active systemic infections (respiratory/urinary tract infections with fever ≥ 38.5°C)
4. organ dysfunctions: hepatic impairment (ALT/AST > 3×ULN [> 80 U/L]) and renal insufficiency (eGFR < 30 mL/min/1.73 m² according to the CKD-EPI formula)
5. hematologic/immunologic disorders: coagulopathy (INR > 1.5, platelets < 100×10^9/L). Immunosuppressive therapy was given within 30 days.
6. local contraindications: skin lesions/infections at the puncture site
7. pregnancy
8. concurrent enrollment in other interventional trials

Table 1. *Demographic data of the studied groups.*

		Group C (n = 30)	Group N (n = 30)	*P*-value
Age (years)		65.80 ± 14.25	66.93 ± 14.08	0.758
Gender	Male	12 (40%)	18 (60%)	0.121
	Female	18 (60%)	12 (40%)	
Weight (kg)		63.03 ± 10.34	64.43 ± 8.25	0.564
Height (cm)		164.23 ± 8.66	162.77 ± 9.24	0.528
Affected side	Right	13 (43.33%)	16 (53.33%)	0.438
	Left	17 (56.67%)	14 (46.67%)	
Time (d)		59.37 ± 59.93	67.07 ± 65.24	0.252

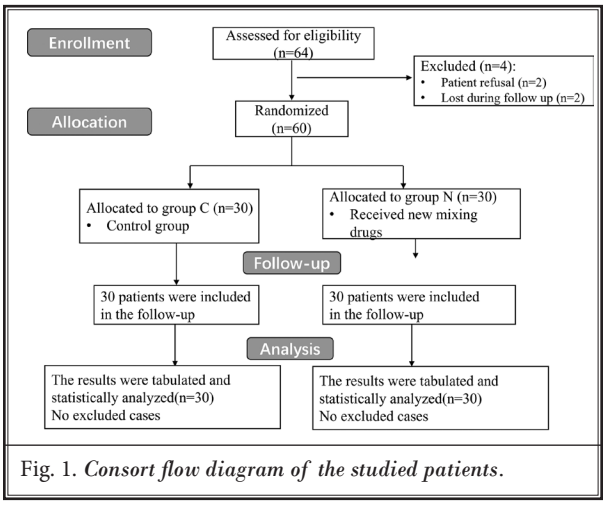

Fig. 1. *Consort flow diagram of the studied patients.*

Monitoring and Thoracic Paravertebral Block

The color US instrument Navi S6 was provided by Wisonic Medical (Shenzhen Wisconic Medical Technology Co., Ltd.). A low-frequency curvilinear transducer (2–5 MHz) was used. The blocks were subjected to strict aseptic protocols, including skin disinfection with 0.5% povidone-iodine solution (Andierdian®, HealthFortis) and sterile probe cover application. All patients were monitored (PM-700 M, Mindray), including pulse oximetry, noninvasive blood pressure measurements, and electrocardiograms. To ensure safety, communication with the patient was maintained at all times during the treatments. Under US-guidance, 15 mL of the assigned mixture was injected below the costotransverse ligament at the affected thoracic segment. All patients were administered 150 mg pregabalin (NE2B4237, Qilu Pharmaceutical [Hainan] Co., Ltd.) capsules orally each day.

Interventional Procedure

After the patient provided signed informed consent, the outpatient surgical treatment room was entered and monitored, and the patient was given a nasal oxygen supplementation (2 L/min). The individual was placed in a prone position to determine the thoracic stage of the lesion nerve for marking. After routine disinfection and laying, the linear low-frequency transducer with a sterile sleeve was placed in parallel on the thoracic vertebra of the lesion segment, and the in-plane technique was adopted. A 20G echogenic needle (80 mm TWL8, KDL Medical) reached below the superior costotransverse ligament (Fig. 2), and 15 mL of mixture was injected, with subpleural expansion as the standard; the puncture point was protected by dressing the application after the treatment. The patient was monitored for a duration of 15 minutes after the transition to a supine posture.

Postoperative Assessments

Patients' pain intensity was determined via the NRS for pain (0 = no pain, while 10 = severe and unbearable pain) prior to the block (baseline). Sleep quality was assessed the Pittsburgh Sleep Quality Index (PSQI) before treatment and at 12 hours and 7 days after treatment. Side effects and complications (nausea, vomiting, constipation, injection site reactions, pneumothorax, local anesthetic toxicity, and respiratory depression) were recorded.

Statistical Analysis

Statistical analysis was performed via SPSS 25.0. For the parametric variables, the Shapiro-Wilk normality independent samples t-test was applied to compare the means and SDs between the 2 groups. For nonparametric variables, the Mann-Whitney U test was used for intergroup comparisons. The frequencies and percentages of categorical variables were calculated, and the Pearson chi-square test was used for comparisons between the groups. Violin plots were used to determine the distribution of the quantitative data. A 2-tailed *P*-value < 0.05 was considered statistically significant.

Results

ZAP, which can progress to PHN (19), is recognized as an intractable neuralgia. Sixty patients were recruited and divided into 2 groups in this work. There were no statistically significant differences between the 2 groups in terms of age distribution, gender ratio, weight, or height. There was no statistically signif-

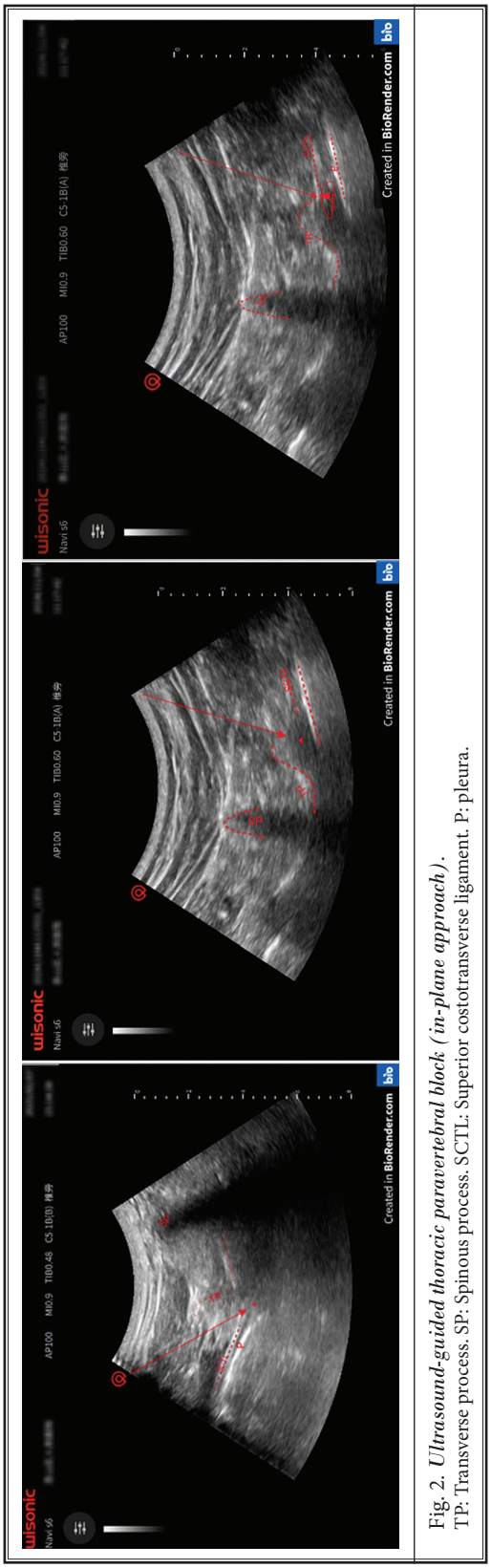

Fig. 2. *Ultrasound-guided thoracic paravertebral block (in-plane approach).*
TP: Transverse process. SP: Spinous process. SCTL: Superior costotransverse ligament. P: pleura.

icant difference in the disease course between the groups ($P > 0.05$). Regarding the affected side, a greater proportion of left-sided involvement was noted in the control group, whereas right-sided predominance was observed in the novel treatment group; however, there was no significant difference between the groups ($P > 0.05$). (Table 1).

Quality of life is significantly affected by HZ. The NRS score is widely regarded as the gold standard for assessing pain (20). For both groups, the NRS scores were significantly lower after treatment than before it, indicating the effectiveness of nerve block therapy in both groups. In Group C, patients' pain scores decreased significantly from their pre-treatment levels at 12 hours after treatment ($P < 0.05$) but increased significantly at 7 days after treatment from the scores reported at that 12-hour mark ($P < 0.05$). These findings suggest that the continued analgesic efficacy of the treatment Group C received diminished after 12 hours. In Group N, the pain scores were significantly lower at 12 hours after treatment than those measured before the treatment ($P < 0.05$), and pain scores assessed at 7 days after treatment were significantly lower than they were at 12 hours following it ($P < 0.05$). The pain was continuously suppressed, and the therapeutic effect was stable during the 7-day observation period. When the 2 groups were compared, no significant difference was observed in the baseline NRS score. Both groups showed significant reductions from baseline at 12 hours after treatment, with no intergroup differences. However, at 7 days after the treatment, Group N presented significantly lower NRS scores than did Group C ($P < 0.05$), meaning that Group N demonstrated superior sustained pain improvement to the control group (Table 2 and Fig. 3).

The PSQI is a widely utilized self-report questionnaire designed to evaluate patients' sleep quality (21,22). As assessed on the PSQI, both groups showed significant improvements in sleep quality from their pretreatment responses after the intervention, indicating the effectiveness of nerve block therapy in both groups. In Group C, the PSQI score decreased significantly from pretreatment to the 12 hours after the treatment ($P < 0.05$), but from that point, the score increased significantly at the 7-day post-treatment mark ($P < 0.05$). This

Table 2. *Numeric rating scale in the studied groups.*

		Before Treatment	12h After Treatment	7d After Treatment
Group C (n = 30)		7.53 ± 0.97	2.57 ± 1.00	3.73 ± 1.05
Group N (n = 30)		7.43 ± 0.97	2.67 ± 0.71	2.33 ± 0.92
P1 value		0.692	0.658	< 0.001***
P2 value	Group C	-	<0.001***	0.122
	Group N	-	<0.001***	< 0.001***
P3 value	Group C	-	<0.001***	< 0.001***
	Group N	-	<0.001***	< 0.001***

***P-value < 0.001 P1: P-value between Group C and Group N. P2: P-value before treatment, 12 hours after treatment, and 7 days after treatment in Group C. P3: P-value before treatment, 12 hours after treatment, and 7 days after treatment in Group N.

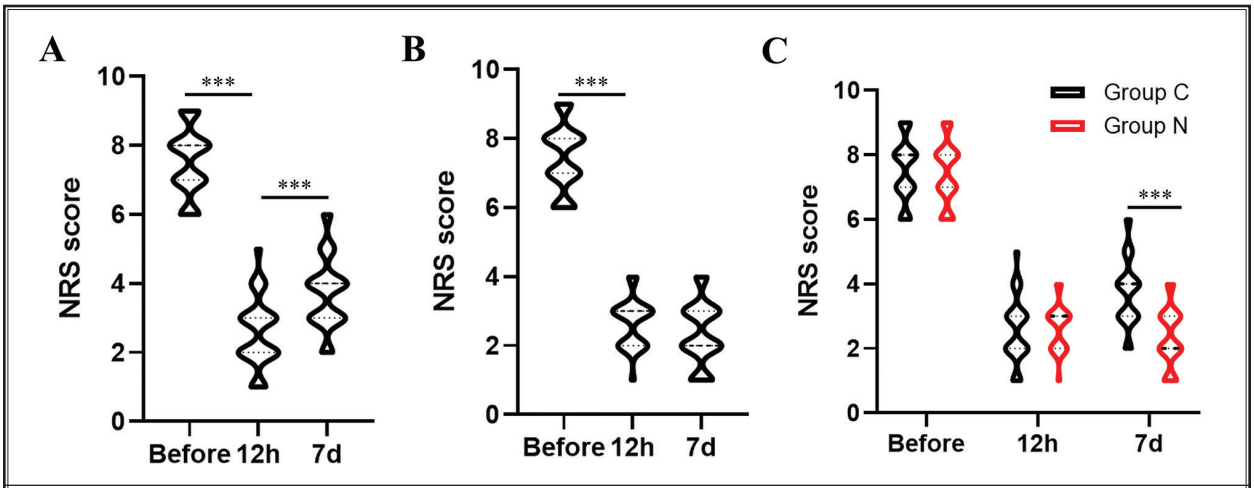

Fig. 3. *Comparative analysis of the numerical rating scale (NRS) in the studied groups. (A) Comparison of the differences in NRS scores at different times in Group C. (B) Comparison of the differences in NRS scores at different times in Group N. (C) Comparison of the differences in NRS scores between Group N and Group C. (***P-value < 0.001.)*

finding suggests that the sustained analgesic efficacy of the treatment in Group C diminished after 12 hours. In Group N, the PSQI score was significantly lower at 12 hours post-treatment than at pretreatment ($P < 0.05$). Compared with those at 12 hours post-treatment, the pain scores were significantly lower at 7 days after the procedure ($P < 0.05$), indicating stable and prolonged therapeutic effects with sustained improvement in sleep quality throughout the 7-day observation period. Intergroup comparisons revealed no significant differences in baseline PSQI scores. Both groups showed significant reductions from baseline at 12 hours after treatment. Meanwhile, Group C presented significantly lower PSQI scores than Group N did at this time point ($P < 0$ .05). However, at 7 days after treatment, Group N demonstrated significantly lower PSQI scores than did Group C ($P < 0.05$). The novel mixture treatment demonstrated better sustained therapeutic effects in the management of pain. These findings suggest that Group C achieved rapid but transient therapeutic effects, whereas Group N represents a more effective and durable treatment modality for sustained pain relief and sleep quality improvement (Table 3 and Fig. 4).

Side effects and complications, such as nausea, vomiting, constipation, injection site reactions, pneumothorax, local anesthetic toxicity, and respiratory depression, were not observed in either group of patients.

Discussion

HZ is caused by reactivation of the varicella-zoster virus and presents as a painful rash called ZAP, which presents as AHN or PHN. Patients with weakened immune function are at increased risk of developing HZ (23). Before the appearance of characteristic maculopapular rashes, patients may present with symptoms, including discomfort, headache, low-grade fever, and abnormal skin sensations, for a duration of 2 to 3 days. This rash, which is characteristically unilateral and confined to a single dermatome (24), usually evolves into transparent vesicles and then becomes cloudy and forms crusts within 7 to 10 days (25). PHN, defined as localized skin-distribution pain that persists for at least 90 days after AHN (26), often presents as persistent burning or stabbing pain and severely affects patients' quality of life, psychological well-being sleep, quality, ability to participate in activities of daily living, and economic status (27).

Management strategies for HZ focus on symptom relief (28). One such strategy is the US-guided TPVB, a simple, novel US-guided block technique (29). Because of the convenience and relative efficacy of this procedure, US-guided nerve blocks have become increasingly prevalent in clinical practice (30,31). TPVB outcomes depend on the blockade level, drug selection, drug concentration, and treatment frequency. The commonly used agents for nerve blocks consist primarily of a combination of corticosteroids and local anesthetics (32), with no standardized guidelines currently established for the optimal ratio between these pharmaceutical components. The first-line medications used include lidocaine, betamethasone (33), ropivacaine (34), methylcobalamin, parecoxib, tricyclic antidepressants (35), pregabalin, and gabapentin. Topical formulations of tramadol and capsaicin, including transdermal patches and analgesic creams, are generally reserved for second- or third-line therapeutic regimens in chronic pain management. However, since a significant proportion of patients fail to achieve adequate pain relief from conservative measures, interventional pain management techniques remain important therapeutic options for refractory cases.

In this study, a compound betamethasone injection at a dose of 0.25 mL was administered in the nerve block regimen, aiming to minimize the impact on blood glucose levels in patients with comorbid diabetes. To achieve a faster onset of action, a low-concentration lidocaine injection was coadministered. The conventional combination for our clinical treatment consisted of 0.25% lidocaine + 1/4 betamethasone + 0.1% ropivacaine + saline. To improve each patient's pain condition, we added 1000 μg of methylcobalamin + 20 mg of parecoxib and performed TPVBs in combination with US technology. The aim of this study was to assess whether the new treatment involving ZAN and PHN yielded more enduring and superior effects than the normal treatment did.

Table 3. *PSQI scores in the studied groups*.

		Before Treatment	12h After Treatment	7d After Treatment
Group C (n = 30)		15.33 ± 2.31	6.13 ± 2.64	10.13 ± 2.08
Group N (n = 30)		15.77 ± 2.70	9.13 ± 2.40	5.40 ± 2.37
P1 value		0.507	< 0.001***	< 0.001***
P2 value	Group C		< 0.001***	< 0.001***
	Group N		< 0.001***	< 0.001***
P3 value	Group C		< 0.001***	< 0.001***
	Group N		< 0.001***	< 0.001***

*** *P*-value < 0.001. P1: *P*-value between Group C and Group N. P2: *P*-value before treatment, 12 h after treatment, and 7 days after treatment in Group C. P3: *P*-value before treatment, 12 hours after treatment, and 7 days after treatment in Group N.

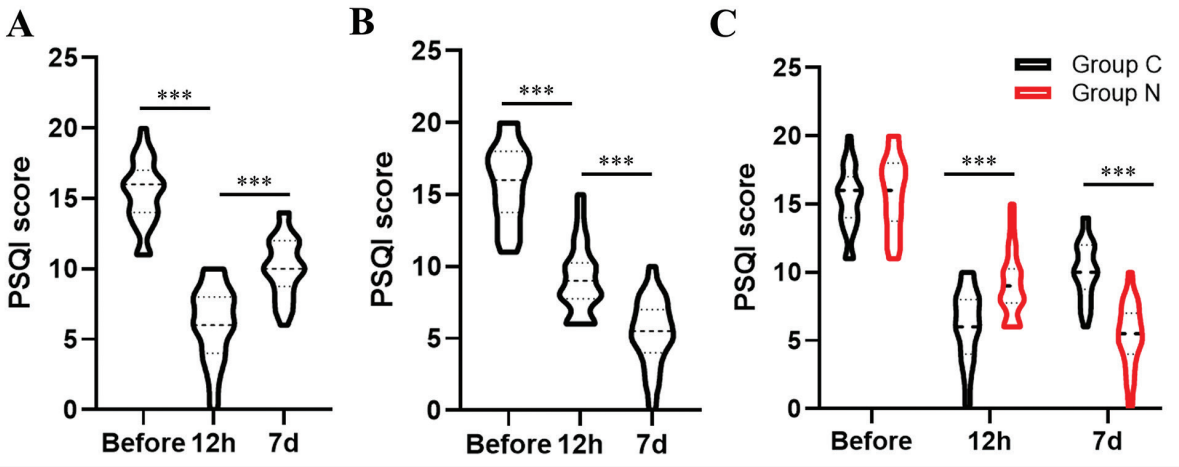

Fig. 4. *Comparative analysis of the Pittsburgh Sleep Quality Index (PSQI) in the studied groups. (A) Comparison of the differences in PSQI scores at different times in Group C. (B) Comparison of the differences in PSQI scores at different times in Group N. (C) Comparison of the differences in PSQI scores between Group N and Group C. (***P-value < 0.001)*

In this study, we focused on patients with thoracic-segment ZAPs who had NRS scores ≥ 6. This study conducted a statistical analysis of the clinical data of 60 enrolled ZAP patients. There was no significant difference in the baseline clinical characteristics between the 2 groups of patients. Following treatment, both groups demonstrated notable decreases in their pain scores. However, the group of patients who received the novel therapeutic agent demonstrated more sustained improvement in pain management. Furthermore, both patient groups demonstrated significant improvements in sleep quality, with the novel-treatment group exhibiting a more pronounced improvement in sleep quality outcomes. Following the integration of the parecoxib sodium injection into the novel treatment protocol, all patients achieved sustained and stable pain relief within 7 days. This randomized clinical trial revealed that, compared to a control treatment, an US-guided TPVB that uses a combination of local anesthetic agents and parecoxib can significantly reduce the incidence of HZ-related pain in patients with acute HZ. However, the precise mechanism remains undetermined, and further research is needed.

Limitations

This study has several limitations. Firstly, its sample size was relatively small. Secondly, the characteristics of the clinical indicators are not rich enough. To provide a clinical evidence–derived basis for the application of novel treatments, we will carry out a multicenter randomized controlled study and simultaneously lay a foundation for the development of standardized guidelines for novel treatments.

Conclusion

Compared to conventional treatments for HZ-related pain, US-guided TPVBs that used the novel drug combination provided more sustained analgesia and greater sleep quality enhancement without additional safety concerns. This optimized formulation represents a promising therapeutic approach for treating thoracic HZ-associated neuralgia.

Acknowledgments

The authors would particularly like to acknowledge their team members and research participants for providing a great deal of support and assistance.

Author Contributions

Dan Li: conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources

Shuai Pan: software, supervision, validation, visualization, writing (original draft)

Zuchao Huang: conceptualization, funding acquisition, project administration

Tiankui Feng: resources, writing (review and editing)

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