

# Effect of Cognitive Behavioral Therapy for Insomnia on Stellate Ganglion Block Treatment for Chronic Insomnia

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**Background:** Chronic insomnia is a prevalent health concern. Treatment methods for chronic insomnia encompass medication therapy, psychotherapy, physical therapy, and sympathetic nerve regulation therapy. The synergistic effects of these various therapeutic approaches warrant further investigation.

**Objective:** This study aims to evaluate the impact of cognitive behavioral therapy for insomnia (CBT-I) in conjunction with stellate ganglion block (SGB) treatment on patients suffering from chronic insomnia.

**Patients and Methods:** Patients diagnosed with chronic insomnia who were admitted to the anesthesia outpatient department between January 2023 and September 2024 were selected for this study. They were divided into two groups: the SGB group (Group S) and the CBT-I combined with SGB group (Group CS). Group S received ultrasound-guided SGB using 0.375% ropivacaine at a volume of 4 mL alternately on both sides, administered twice weekly over a period of 6 weeks. Group CS underwent CBT-I concurrently with SGB following the same protocol as Group S for 6 weeks. The Insomnia Severity Index (ISI), Epworth Sleepiness Scale (ESS), and hypnotic medication were recorded before treatment as well as at 6 weeks and 12 weeks after treatment.

**Results:** The ISI and ESS scores were significantly decreased than before treatment at 6 weeks after treatment in group S ( $P < 0.05$ ), and the ISI and ESS scores were significantly decreased than before treatment at 6 and 12 weeks after treatment in group CS ( $P < 0.05$ ). The ISI and ESS scores were significantly lower in group CS than in group S at 6 and 12 weeks after treatment ( $P < 0.05$ ). The hypnotic medication was also significantly lower in group CS than in group S at 12 weeks after treatment ( $P < 0.05$ ).

**Conclusion:** CBT-I substantially enhances the efficacy of stellate ganglion block treatment for chronic insomnia, reducing reliance on hypnotic medications; furthermore, sustains stable long-term outcomes.

**Keywords:** chronic insomnia, cognitive behavioral therapy, stellate ganglion block, hypnotic medication, effect

## Introduction

Insomnia is the most prevalent sleep disorder, affecting approximately 9% to 15% of the population.<sup>1</sup> It is primarily characterized by difficulties in initiating sleep, maintaining sleep, and experiencing early awakenings. Insomnia may also be accompanied by daytime dysfunction. When insomnia persists for more than three months, it is classified as chronic insomnia. Chronic insomnia can lead to significant health risks and socio-occupational impairments, imposing a substantial burden on both the patient's family and society at large, thus rendering it a serious global public health issue.<sup>2</sup>

Currently, the primary treatment modalities for chronic insomnia encompass pharmacologic and non-pharmacologic approaches. While pharmacologic treatments can enhance sleep quality in the short term, they are associated with adverse drug reactions such as dizziness, residual sedation (hangover effect), and potential drug dependence. Consequently, long-term use of pharmacologic interventions for chronic insomnia is not recommended.<sup>3</sup> Most patients suffering from chronic insomnia exhibit heightened excitation of autonomic nervous system function. Stellate ganglion block (SGB) has been demonstrated to alleviate sympathetic nervous system tension;<sup>4</sup> regulate the body's autonomic

nervous system along with its endocrine and immune systems; and maintain dynamic equilibrium.<sup>5</sup> SGB has been utilized in treating chronic insomnia;<sup>6</sup> however, the stability and durability of its therapeutic effects remain uncertain.

Cognitive Behavioral Therapy for Insomnia (CBT-I) forms part of a psychological-cognitive-behavioral treatment model aimed at modifying patients' belief systems while enhancing self-efficacy to improve symptoms of insomnia. CBT-I is endorsed by both domestic and international guidelines as the preferred intervention for managing chronic insomnia;<sup>7-9</sup> however, its impact on augmenting the efficacy of SGB in treating this condition has yet to be established. To address this knowledge gap, this study aims to investigate the effect of CBT-I on SGB in treating chronic insomnia.

## Patients and Methods

### Study Patients

This study received approval from the Ethics Committee of Hangzhou Third People's Hospital (2024KA114) and registered with the Chinese Clinical Trial Registry (ChiCTR2500103697), conducted in accordance with the Declaration of Helsinki. All patients underwent psychiatric evaluation by the attending psychiatrist in the Department of Mental Health and provided written informed consent.

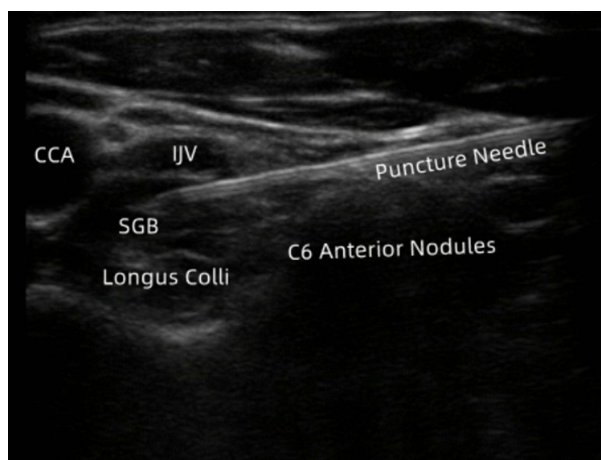
A total of 124 patients diagnosed with chronic insomnia, who were admitted to our hospital's anesthesia sleep clinic between January 2023 and September 2024, participated in this study. The inclusion criteria were as follows: (1) patients aged  $\geq 18$  years, regardless of sex; (2) fulfillment of the diagnostic criteria for chronic insomnia as outlined in the third edition of the International Classification of Sleep Disorders.<sup>10</sup> The exclusion criteria included: (1) inability to understand or cooperate with the treatment program; (2) major anxiety disorder, major depressive disorder, schizophrenia, and/or bipolar disorder; (3) other types of sleep disorders such as sleep apnea syndrome, restless legs syndrome, or circadian rhythm disorders; (4) shift work, year-round night-shift work, and/or frequent flights across time zones; (5) pregnancy, breastfeeding, or plans to become pregnant; (6) alcohol or substance abuse issues; and (7) coagulation disorders. Patients were randomized into two groups: SGB group (Group S) and CBT-I combined with SGB group (Group CS), using a computer-generated randomization list. In Group S, 4 patients requested discontinuation from the study and 2 patients modified their treatment regimens. In Group CS, 2 patients requested discontinuation from the study, 3 patients modified their treatment regimens, and 1 patient exhibited incomplete follow-up data. Ultimately, each group comprised 56 participants.

### Ultrasound-Guided Stellate Ganglion Block

Patients in group S underwent ultrasound-guided stellate ganglion block (SGB).<sup>11</sup> The patient was instructed to lie flat on the treatment bed, and electrocardiographic monitoring was initiated. The neck area was exposed, allowing for visualization of the C6 anterior nodules and the longus colli using a Myriad high-frequency probe. The physician utilized a 25-G puncture needle, inserting it in-plane relative to the surface of the longus colli while slowly injecting 4 mL of 0.375% ropivacaine (Figure 1). The onset of Horner's syndrome was considered an indicator of successful blockade. Patients received SGB alternately on the right and left sides twice weekly for a duration of 6 weeks.

### Cognitive Behavioral Therapy for Insomnia

Group CS underwent SGB treatment utilizing the same methodology as described for group S, in conjunction with a 6-week course of Cognitive Behavioral Therapy for Insomnia (CBT-I). CBT-I encompasses several components including sleep restriction, stimulus control, education on sleep hygiene, relaxation training, and cognitive therapy.<sup>12</sup> In week 1, patients were introduced to the fundamental concepts of CBT-I and instructed on how to maintain a sleep diary. They also received education regarding proper sleep hygiene practices. In week 2, baseline sleep patterns were assessed and erroneous behaviors identified through the analysis of their sleep diaries were addressed. The principles and application of stimulus control and sleep restriction were subsequently introduced. For stimulus control, patients were advised to go to bed only when they felt an urge to sleep; if they could not fall asleep within 20 minutes while in bed, they were instructed to leave the bed until they felt sleepy again. Additionally, patients were required to adhere to a consistent wake-up time. Every weekend, adjustments to total sleep duration were made based on each patient's weekly sleep diary entries. Specifically, if the patient's sleep efficiency exceeded 85%, their time in bed was increased by



**Figure 1** Images of ultrasound-guided SGB.

**Abbreviations:** CCA, common carotid artery; IJV, internal jugular vein; SG, stellate ganglion.

15 minutes; if it ranged between 80%–85%, no changes were made; whereas if it fell below 80%, their time in bed was reduced by 15 minutes. Patients also learned abdominal breathing techniques and meditation practices. In week 3, adherence levels to CBT-I protocols were evaluated alongside instruction in progressive muscle relaxation techniques. A sleeping schedule along with a plan for reducing hypnotic medication usage was developed for implementation during the following week. During weeks 4–5, assessments of patients' previous week's sleeping patterns took place using data derived from their diaries. The influence of maladaptive beliefs about sleep and negative emotional states on overall sleeping quality was examined thoroughly. Efforts focused on reconstructing accurate perceptions surrounding healthy sleeping habits while formulating plans for continued reduction of both insomnia symptoms and reliance on hypnotic medications moving forward into subsequent weeks. In week 6, the treatment process was comprehensively summarized and analyzed, the efficacy of the treatment was evaluated, and patients were educated on insomnia management strategies as well as methods to prevent recurrence. Patients were encouraged to consistently maintain healthy sleep habits and accurate sleep cognition, adhere to the prescribed hypnotic medication reduction plan, and attend regular follow-up appointments at the outpatient clinic.

## Hypnotic Medication

All patients were able to reduce their long-term hypnotic medication based on sleep quality after 2 weeks of treatment, with a gradual reduction of the initial hypnotic dosage by 10%–25% every two weeks.<sup>13</sup> Participants were informed that the emergence of specific symptoms—such as rebound insomnia, muscle tension, weakness, anxiety, panic disorder, blurred vision, dry mouth, and tinnitus—might indicate withdrawal effects.<sup>14</sup> Rebound insomnia was identified as the primary withdrawal symptom; if this symptom became intolerable, the dosage would be reinstated to the level from the previous two weeks. The dosage could either revert to its initial amount or even be increased if necessary. In cases where symptoms persisted or worsened, prompt medical assistance should be sought.

## Outcomes

Demographic characteristics assessed included age, gender, duration of insomnia, marital status, education level, employment status, and consumption of tea, tobacco, alcohol, and coffee over the past year. The Insomnia Severity Index (ISI, a seven-item self-report scale designed to evaluate the severity of insomnia experienced over the preceding two weeks; it demonstrates good reliability and validity, each item is rated on a five-point Likert scale ranging from 0 (none) to 4 (high severity), yielding a total score that ranges from 0 to 28),<sup>15</sup> the Epworth Sleepiness Scale (ESS, consists of eight items aimed at assessing daytime sleepiness severity; each item is scored from 0 (never doze) to 3 (high chance of dozing), total scores range from 0 to 24; higher scores indicate greater levels of sleepiness)<sup>16</sup> and hypnotic medication were evaluated before treatment and again at 6 weeks and 12 weeks after treatment.

## Statistical Analysis

SPSS 20.0 software (SPSS, Illinois, US) was used for the statistical analysis, and GraphPad Prism 5.0 software was used for plotting the charts. The Kolmogorov–Smirnov test was used to evaluate the normal distribution of the measurement data. The results are expressed as the mean  $\pm$  SD. Inter-group comparisons were performed using the group *t*-test, while intra-group comparisons were performed using repeated-measures analysis of variance. Counting data are expressed as rates and percentages, and comparisons were made using the  $\chi^2$ -test. The rank-sum test was used to compare the grade data.  $P < 0.05$  was considered statistically significant for all tests.

## Results

There were no significant differences in the basic characteristics of the patients between the two groups ( $P > 0.05$ ) (Table 1). Compared with before treatment, the ISI and ESS scores were decreased at 6 weeks after treatment in group S ( $P < 0.05$ ), the ISI and ESS scores were no statistically significant difference at 12 weeks after treatment in group S ( $P > 0.05$ ), and the ISI and ESS scores were decreased at both 6 weeks and 12 weeks after treatment in group CS ( $P < 0.05$ ). Compared with group S, the ISI and ESS scores were significantly lower at 6 weeks and 12 weeks after treatment in group CS ( $P < 0.05$ ) (Table 2), hypnotic medication was significantly lower at 12 weeks after treatment in group CS ( $P < 0.05$ ) (Table 3).

**Table 1** Basic Characteristics of the Participants (n=56)

General Conditions	Group S	Group CS	$\chi^2/t$ -Value	P-Value
Age, (years, Average $\pm$ SD)	44.3 $\pm$ 9.5	42.4 $\pm$ 10.4	0.966	0.336
Gender, n(%)			0.996	0.318
Male	22(39.3%)	16(28.6%)		
Female	34(60.7%)	40(71.4%)		
Duration of insomnia, (years, Average $\pm$ SD)	4.3 $\pm$ 2.3	4.8 $\pm$ 2.2	0.792	0.233
Marital status, n(%)			1.326	0.249
Lone	9(16.1%)	15(26.8%)		
Married	47(83.9%)	41(73.2%)		
Education degree, n(%)			0.596	0.441
Postsecondary or less	11(19.6%)	7(12.5%)		
Bachelor or above	45(80.4%)	49(87.5%)		
Employment, n(%)			0.394	0.531
Full-time	42(75%)	38(67.9%)		
Retired/unemployed	14(25%)	18(22.1%)		
Drinking in the last year, n(%)			1.212	0.271
No /Rarely	54(96.4%)	50(89.3%)		
Frequent (three or more times a week)	2(3.6%)	6(10.7%)		
Smoking in the last year, n(%)			0.176	0.679
No /Rarely	52(92.9%)	54(96.4%)		
Frequent (three or more times a week)	4(7.1%)	2(3.6%)		
Drinking coffee in the last year, n(%)			0.403	0.527
No /Rarely	52(92.9%)	49(87.5%)		
Frequent (three or more times a week)	4(7.1%)	7(12.5%)		
Drinking tea in the last year, n(%)			0.483	0.489
No /Rarely	53(94.6%)	50(89.3%)		
Frequent (three or more times a week)	3(5.4%)	6(10.7%)		
Use of hypnotic medication in the last year, n(%)			0.277	0.599
No /Rarely	10(17.9%)	7(12.5%)		
Frequent (three or more times a week)	46(82.1%)	49(87.5%)		

**Table 2** Comparison of ISI and ESS Before and After Treatment in Two Groups (n=56)

Outcome Assessments	Group S	Group CS	t-Value	P-Value
ISI				
Before treatment	20.5±2.8	21.2±2.9	-1.387	0.168
6 weeks after treatment	14.9±2.3 <sup>a</sup>	8.4±2.3 <sup>ab</sup>	13.836	<0.001
12 weeks after treatment	19.9±2.3	6.5±2.3 <sup>ab</sup>	30.732	<0.001
ESS				
Before treatment	6.6±1.9	6.6±2.3	0.432	0.666
6 weeks after treatment	5.7±1.5 <sup>a</sup>	3.1±1.4 <sup>ab</sup>	9.964	<0.001
12 weeks after treatment	6.1±1.4	2.8±1.0 <sup>ab</sup>	13.982	<0.001

Notes: <sup>a</sup>P < 0.05 vs before treatment; <sup>b</sup>P < 0.05 for Group CS vs Group S.

**Table 3** Comparison of Hypnotic Medication After Treatment in Two Groups (n=56)

Time	Group	None/Stop	Reduce	Invariant	Rise	W	P-Value
6 weeks after treatment	Group S n(%)	10(17.9%)	26(46.4%)	17(30.3%)	3(5.4%)	3112	0.333
	Group CS n(%)	7(12.5%)	33(58.9%)	15(26.8%)	1(1.8%)		
12 weeks after treatment	Group S n(%)	14(25%)	17(30.3%)	20(35.8%)	5(8.9%)	2369	<0.05
	Group CS n(%)	37(66%) <sup>a</sup>	15(26.8%) <sup>a</sup>	3(5.4%) <sup>a</sup>	1(1.8%) <sup>a</sup>		

Note: <sup>a</sup>P < 0.05 for Group CS vs Group S.

## Discussion

This study demonstrated that SGB exhibited transient efficacy in the treatment of chronic insomnia. Furthermore, CBT-I significantly enhanced the effectiveness of SGB for managing chronic insomnia, leading to a durable and stable improvement in sleep quality while reducing the reliance on hypnotic medications.

The stellate ganglion (SG) is a component of the cervical sympathetic nervous system, formed by the fusion of the inferior cervical ganglion and the first thoracic vertebrae ganglion. The stellate ganglion block (SGB) involves the injection of local anesthetic agents into the surrounding tissues of the SG to modulate thalamic activity, maintain homeostasis within the body, adjust sympathetic nervous system tension, and ultimately regulate various systems including the autonomic nervous system, circulatory system, endocrine system, and immune system to achieve dynamic equilibrium.<sup>17</sup>

In this study, both ISI and ESS scores showed significant reductions after SGB over a 6-week period in group S, indicating an improvement in sleep quality. Liu<sup>18</sup> found that patients with insomnia exhibited a significantly lower Pittsburgh Sleep Quality Index score 4 weeks post-SGB treatment compared to baseline levels. Furthermore, Gu<sup>19</sup> reported that elderly patients suffering from chronic insomnia experienced markedly improved sleep quality at 30 days following SGB treatment—results consistent with those observed in our current study. These findings suggest that SGB may provide reliable short-term efficacy for treating chronic insomnia. SGB has been proposed to decrease secretion levels of adrenocorticotrophic hormone-releasing hormone as well as norepinephrine and epinephrine; these changes may facilitate recovery of melatonin physiological rhythms thereby alleviating sleep rhythm disorders and disturbances.<sup>20,21</sup> However, it is noteworthy that neither Liu nor Gu conducted long-term follow-up assessments regarding efficacy. In contrast to previous studies' findings on short-term benefits from SGB treatment for chronic insomnia, our investigation revealed a dramatic increase in ISI and ESS scores among patients in group S 12 weeks after treatment; notably their sleep quality deteriorated back to prior poor levels. This observation indicates that while SGB may offer temporary relief for chronic insomnia symptoms, it lacks stable long-term effectiveness. This limitation could be attributed partly to chronic insomnia being not solely a neuroendocrine disorder but also influenced by multifaceted social and psychological

factors. We recommend that clinicians refrain from utilizing SGB as the sole intervention for chronic insomnia. Instead, a multidisciplinary, multimodal, and comprehensive treatment strategy should be implemented.

CBT-I aims to modify unhealthy long-term sleeping habits and the cognitive patterns of patients suffering from chronic insomnia. The discomfort associated with this treatment modality has historically resulted in a lower completion rate among patients during the initial stages, thereby impacting overall efficacy.<sup>22,23</sup> In this study, we observed that the ISI and ESS scores for patients in group CS significantly decreased at both 6 weeks and 12 weeks after treatment compared to baseline measurements. Furthermore, the effectiveness of the combined treatment (CBT-I + SGB) was markedly superior to that of SGB alone, leading to a consistent improvement in sleep quality. In group CS, patients were introduced to the principles of CBT-I as well as instructed on maintaining sleep diaries throughout their SGB treatment. SGB provides rapid regulation effects on the nervous system; recognizing these therapeutic benefits can enhance patient confidence and resilience against various discomforts arising from sleep restriction or stimulation control employed during CBT-I. This increased confidence may subsequently improve adherence to CBT-I practices.<sup>24</sup> With the implementation of CBT-I, compliance with behavioral and cognitive restructuring techniques has progressively improved,<sup>25,26</sup> offering a long-term and stable solution for achieving high-quality sleep.

The ESS serves as a valuable instrument for assessing daytime sleepiness and functional status. However, its reliance on subjective self-assessment may be influenced by factors such as memory bias, individual differences in perception, or variations in cognitive capacity, which could introduce potential inaccuracies in measurement. Hunasikatti<sup>27</sup> argues that the ESS alone is inadequate as a precise measure for evaluating treatment outcomes and underscores the necessity of establishing the minimum clinically important difference (MCID) to facilitate more clinically meaningful assessments. Patel et al<sup>28</sup> estimated that the MCID for the ESS among patients with obstructive sleep apnea (OSA) ranges from  $-2$  to  $-3$ . Meanwhile, Crook et al<sup>29</sup> suggested employing a minimal important difference (MID) of 2 points for the ESS in OSA patients. Our study concentrated on individuals diagnosed with primary insomnia, a clinical condition distinct from obstructive sleep apnea. The participants were predominantly characterized by elevated ISI scores coupled with relatively low ESS scores; specifically, the average ESS score across both groups prior to treatment was 6.6. In comparison to the S group, the CS group exhibited an average improvement of  $-2.5$  at 6 weeks after treatment and  $-3.6$  at 12 weeks after treatment regarding their ESS scores. When compared to the S group, those in the CS group demonstrated an average improvement of  $-2.6$  at 6 weeks and  $-3.3$  at 12 weeks after treatment—essentially meeting MCID criteria. Notably, symptoms associated with daytime sleepiness have shown significant enhancement throughout this period; we contend that these findings retain substantial clinical relevance.

The ISI is a valuable clinical instrument utilized both as a screening tool for patients presenting with insomnia symptoms and as an outcome measure in research studies. The average ISI score for both groups prior to treatment exceeded 20. In comparison to the S group, the CS group exhibited an average improvement in ISI scores of  $-12.8$  at 6 weeks after treatment and  $-15.7$  at 12 weeks after treatment. When compared to the S group, the CS group's average ISI score improvement was  $-6.5$  at 6 weeks after treatment and  $-13.4$  at 12 weeks after treatment.

Patients experiencing moderate to severe insomnia exhibited a progressive improvement, transitioning towards mild insomnia or even achieving full remission. These findings hold significant implications for clinical treatment planning and intervention strategies. Long-term use of hypnotic medications can substantially increase the risk of cognitive impairment, psychomotor disorders, dementia, and mortality;<sup>30</sup> therefore, it is recommended that patients with chronic insomnia gradually taper off their hypnotic medications.<sup>7</sup> Withdrawal from these medications may be accompanied by withdrawal symptoms, primarily manifesting as somatic symptoms (eg, flu-like symptoms, muscle spasms) and/or psychiatric symptoms (eg, insomnia, anxiety, irritability, perceptual disturbances). These withdrawal symptoms are generally most pronounced at the end of the second week post-withdrawal,<sup>31</sup> often leading many patients to abandon their cessation efforts at this stage. In the present study, we initiated a reduction in hypnotic medication 2 weeks after treatment commenced. Subsequently, patients demonstrated gradual improvements in sleep quality and developed confidence in reducing their medication intake. We observed that the withdrawal symptoms associated with decreasing or discontinuing hypnotic medication were mild and could be effectively managed with medical support. The role of SGB modulation of autonomic function in alleviating withdrawal symptoms warrants further clinical investigation and mechanistic studies. At 12 weeks after treatment evaluation revealed that only 37.5% of patients in group S had reduced

or ceased their use of hypnotic medication compared to 80.4% in group CS. This discrepancy can largely be attributed to patients in group S resuming hypnotics when their sleep quality deteriorated back to previous poor levels during the later stages of treatment; conversely, participants in group CS experienced steady improvements in sleep quality such that reducing or discontinuing hypnotics did not adversely affect their overall sleep experience. Therefore, patients in the CS group successfully attained a significant reduction and cessation of hypnotic medication, thereby restoring their natural sleep patterns.

This study presents several limitations that warrant consideration. The sleep quality was assessed based on patients' subjective scores, we did not conduct polysomnography to objectively evaluate the outcomes. Additionally, we did not establish a standalone CBT-I group due to the exceptionally low completion rate of CBT-I as a monotherapy in our region, which may be influenced by various factors including age, educational background, health literacy levels, trust in treatment, and financial constraints. Patients frequently discontinue treatment before therapeutic effects become apparent (typically within two weeks), resulting in a limited sample size and complicating comparative studies. In future research endeavors, we plan to engage well-trained mental health professionals or psychotherapists to facilitate the development of a peer-supported CBT-I group. This initiative aims to enhance treatment adherence and enable more robust comparisons of therapeutic outcomes. Furthermore, we may investigate whether SGB as an invasive treatment modality can improve both the completion rate and therapeutic efficacy of CBT-I.

## Conclusion

In the management of chronic insomnia, standalone SGB therapy has been found to lack sustained therapeutic effects; therefore, sympathetic nerve modulation techniques are not recommended as monotherapy. CBT-I has demonstrated a significant enhancement in the efficacy of SGB, leading to improved sleep quality and facilitating a stable and comfortable reduction or discontinuation of hypnotic medications. These findings suggest that a comprehensive, multi-modal approach to treating chronic insomnia may be essential for achieving optimal clinical outcomes.

## Data Sharing Statement

Data used to support the findings of this study are available from the corresponding author upon request.

## Ethical Approval

The Ethics Committee of Hangzhou Third People's Hospital (2024KA114) and Chinese Clinical Trial Registry (ChiCTR2500103697) approved this research.

## Informed Consent

Informed consent was obtained from all individual participants included in the study.

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All authors had complete access to the data and were involved in all analyses. The corresponding author reviewed and approved the final version and has final responsibility for the decision to submit this manuscript for publication. We would like to thank the editorial board for their review and criticism in improving this manuscript.

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## Disclosure

The authors declare that they have no competing interests in this research.

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