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Impact of transcutaneous auricular vagus nerve stimulation on postoperative pain in patients undergoing perianal surgery: a randomized trial

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ABSTRACT

Objective: This study aims to evaluate the effectiveness of transcutaneous auricular vagus nerve stimulation (taVNS) on postoperative pain in patients following perianal surgery.

Methods: 96 patients were randomly assigned to either the taVNS group or the sham stimulation group. Patients received stimulation once 30 min before the operation and once more 24 h after the operation, with each session lasting 30 min. The VAS scores were recorded at 2, 6, 24, 48, and 72 h, as well as 7 days postoperatively. Data were collected on the first change of dressing, the first defecation, the frequency of supplementary analgesia, and the occurrence of adverse reactions. Patient satisfaction was assessed at the time of hospital discharge.

Results: The VAS scores of patients in the taVNS group were significantly lower than those in the sham stimulation group at 2, 6, 24, 48, and 72 h postoperatively, at the time of the first dressing change, and at the time of the first defecation ($p < 0.05$). The rate of postoperative supplementary analgesic use was significantly higher in the sham stimulation group compared to the taVNS group ($p < 0.05$). The incidence of urinary retention was lower in the taVNS group ($p < 0.05$). No adverse reactions like hypotension or bradycardia were observed in either group. Patient satisfaction was higher in the taVNS group ($p < 0.05$).

Conclusion: taVNS effectively alleviates postoperative pain in patients undergoing perianal surgery without increasing the risk of complications.

Abbreviations: taVNS: transcutaneous auricular vagus nerve stimulation; VAS: visual analogue scale; ASA: American Society of Anesthesiologists; PCA: patient controlled analgesia

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1. Introduction

Perianal diseases and disorders like haemorrhoids, anal fissures, anal fistulas, and perianal abscesses, are highly prevalent in clinical practice. Survey results on anal and intestinal disorders in China indicate an overall incidence rate of approximately 59.1%, with haemorrhoids comprising about 87.25% of these cases [1]. The incidence of anal fistulas is second only to haemorrhoids, ranging from 1.67% to 3.60% in the population [2]. The prevalence of perianal abscesses is 2%, and the incidence of fistula formation following an abscess is 15.5% [3].

Surgery represents an effective treatment for perianal diseases. However, due to the dense concentration and sensitivity of nerve endings in the perianal region, many patients often endure significant postoperative pain. Based on a previous study conducted by our team, more than 60% of patients reported experiencing moderate to severe pain seven days following perianal surgery [4]. Inadequate pain management during the perioperative period can potentially lead to heightened complications like urinary retention, bowel obstruction, nausea, vomiting, sleep disturbances, prolonged hospital stays, and chronic pain [5,6]. Reducing postoperative

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pain in perianal surgery remains a prominent and challenging clinical issue [7].

Currently, several methods are used to alleviate postoperative pain following perianal surgery, including oral analgesics like non-steroidal anti-inflammatory drugs (NSAIDs), opioids, patient-controlled analgesia (PCA), herbal fumigation, and topical ointments [8,9]. However, the gastrointestinal side effects associated with NSAIDs, as well as their potential cardiovascular risks and other adverse effects, present significant concerns. Opioids are frequently used for managing severe pain but often induce undesirable effects like nausea, vomiting, and respiratory depression, thereby restricting their application. Topical medications also yield inconsistent outcomes [10]. Effective management of postoperative pain in patients undergoing perianal surgery, particularly during dressing changes and defecation, remains a persistent challenge.

Transcutaneous auricular vagus nerve stimulation (taVNS) is a non-invasive and convenient clinical intervention known for its ability to regulate autonomic function, reduce inflammation, and enhance mood [11,12]. In recent years, taVNS has been increasingly used in the treatment of autoimmune diseases, depression, insomnia, and other conditions [13–15]. Recent studies have indicated that taVNS may provide analgesic benefits through diverse mechanisms like inflammation reduction, modulation of the locus coeruleus-norepinephrine signalling pathway in subcortical regions, and activation of serotonergic and endorphinergic pathways associated with pain relief [16–18]. Despite these findings, there are no studies investigating the application of taVNS for perioperative analgesia in anorectal surgery.

In this prospective randomized controlled trial, the objective was to assess the impact of taVNS on postoperative pain in patients following perianal surgery.

2. Methods

2.1. Study design

This single-centre randomized controlled trial included adult patients who underwent perianal surgery at Shuguang Hospital, Shanghai University of Traditional Chinese Medicine. Ethical approval for the study protocol was provided by the Ethics Committee of Shuguang Hospital, Shanghai University of Traditional Chinese Medicine (No. 2024-1495-078-01). The trial was also registered with the Chinese Clinical Trial Registry (registration number: ChiCTR2400084004). We conducted this study in accordance with the Consolidated Standards of Reporting Trials guidelines.

2.2. Patient recruitment

Inclusion Criteria: Patients with American Society of Anesthesiologists (ASA) physical status I-II, aged 18 years and older, diagnosed with mixed haemorrhoids, anal fissure, anal fistula, or perianal abscess, and who underwent elective perianal surgery (mixed haemorrhoidectomy, anal fistula excision, anal fissure excision, and perianal abscess incision and drainage).

Exclusion Criteria: (1) Chronic preoperative pain or a history of long-term analgesic use; (2) previous perianal surgery; (3) psychiatric diseases; (4) Skin diseases affecting the auricular region; (5) Neuromuscular diseases; (6) Severe hepatic and renal insufficiency; (7) Participation in other concurrent clinical trials; and (8) Refusal to cooperate with the study due to communication difficulties or other reasons.

2.3. Randomization and blinding

After obtaining written informed consent, patients were randomly assigned (1:1) to either the taVNS group or the sham stimulation group using the SPSS random number table. Participants, outcome assessors, and statisticians were blinded to the treatment assignment throughout the data collection and analysis process.

2.4. Interventions

The patients were admitted to the anaesthesia preparation room 30 min before surgery. Upon admission, they received oxygen *via* a mask (2 L/min), an intravenous infusion of sodium lactate Ringer's solution, and underwent continuous monitoring—electrocardiogram, blood pressure, and pulse oximetry.

Both taVNS and sham stimulation were administered using headphone-shaped stimulators (T0138, Xinzile Medical Device, Jiangxi, China) placed on bilateral tragus and cymba conchae. The stimulation protocol chosen for this study, including stimulation time and stimulation parameter settings, was referenced from the article published by Patel et al. [19] Stimulation was conducted once 30 min prior to surgery and again 24 h following surgery, with each session lasting for 30 min.

In the taVNS group: stimulation was initiated at 10 mA using electrical parameters (pulse duration: 200 μs, frequency: 30 Hz), and continued until participants reported feeling a 'tingling sensation' within 20 s of initiation. Once the tingling sensation was reported, the current was adjusted to a level slightly below the threshold (20–60 mA) [19].

In the sham stimulation group, stimulation was started at 10 mA using electrical stimulation parameters (pulse duration: 200 μs, frequency: 30 Hz), and continued until the participant reported a 'tingling sensation' within 20 s of initiation. Upon experiencing this sensation, the current was promptly discontinued [19].

2.5. Anaesthesia and postoperative analgesia

The anaesthesia regimen for both groups involved intravenous anaesthesia combined with nerve block. Anaesthesia induction included propofol (2.5 mg/kg) and sufentanil (0.1 μg/kg). Following induction and patient sedation, bilateral pubic nerve blocks were performed using the ultrasound-guided pubic nerve block method [20]. The local anaesthetic mixture used for the block was 0.2% ropivacaine with epinephrine (10 μg/mL) in a total volume of 20 mL. Anaesthesia maintenance consisted of propofol infusion at a rate of 6.0 to 12.0 mg/(kg·h). Throughout the surgery, vital signs were closely monitored, and medication adjustments were made in response to respiratory and circulatory changes. Postoperatively, routine intravenous administration included 30 mg of ketorolac and 5 mg of tropisetron hydrochloride for analgesia and prevention of nausea and vomiting. Oral paracetamol was prescribed as one tablet (450 mg) twice daily, with an option for an additional dose if severe pain occurred, not exceeding four tablets per day. Rectal suppositories containing artificial musk and artificial bezoar (MaYingLong ZhiChuangShuan) were recommended at one tablet (330 mg) twice daily for their heat-clearing and pain-alleviating properties. In cases of severe pain, oral tramadol tablets (50 mg) were administered with a maximum daily dosage of two tablets.

2.6. Surgical procedures

Both groups followed standard surgical protocols:

Mixed Haemorrhoidectomy: The Milligan–Morgan technique was used, involving external haemorrhoid excision and internal ligation. The external haemorrhoid was incised, and the venous plexus and subcutaneous tissues were stripped up to the dentate line. The base was ligated, and the perianal wound was left open without suturing.

Anal Fistulectomy: The fistula tract was identified and completely excised along its outer wall. Normal skin and subcutaneous tissues overlying the fistula were either preserved or removed as needed.

Anal Fissure Excision: A triangular incision was made along the fissure edge, extending toward the dentate line. The fissure, including the anal sinus and hypertrophic papillae, was excised to create a smooth, flat wound for drainage.

Perianal Abscess Drainage: A radial incision was made at the most fluctuant or bulging area of the abscess. Pus was drained, necrotic tissue was removed, and drainage strips or tubes were placed.

2.7. Pain scoring

The Visual Analog Scale (VAS) was used to assess pain intensity in both groups. A horizontal line was presented on a sheet of white paper, with one end marked as 0 to signify no pain, and the opposite end marked as 10 to denote severe and intolerable pain. Patients were instructed to indicate their perceived level of pain by marking a point on the line that aligned with their pain sensation.

2.8. Outcome indicators

Primary outcome: The VAS score at the time of the first dressing change, which was performed by the surgeon 24 h postoperatively.

Secondary outcomes: VAS scores at rest at 2, 6, 24, 48, and 72 h postoperatively, as well as at 7 days postoperatively; VAS scores at the time of the first postoperative defecation; the average daily paracetamol consumption (tablets/day) per person and the frequency of adjunctive analgesia during the 7 days postoperatively were recorded.

Other secondary outcomes: Time to the first postoperative defecation, frequency of defecation per day, incidence of perioperative adverse events (like nausea and vomiting, urinary retention, skin burns on the auricular region, itching, headache, hypotension, bradycardia), and patient satisfaction at discharge (categorized as satisfied, basically satisfied, or dissatisfied).

2.9. Statistical methods

Sample Size Calculation for Patients: in the pilot study involving 15 patients, the expected values for outcome indicators are 3.2 ± 1.5 for VAS in the taVNS group and 4.1 ± 1.5 for VAS in the sham stimulation group. With a two-tailed test level of α = 0.05, a degree of certainty of 1 − β = 0.8, each group required 44 patients according to the formula. Considering an anticipated loss rate of 10%, the final sample size required was 96 participants.

The reason for the discrepancy between the sample size and the registration form is: The preliminary experimental results showed that taVNS can effectively alleviate postoperative pain after perianal surgery, and the sample size calculated based on the preliminary experimental results can be slightly reduced.

Data Analysis: Data were analyzed using SPSS 25.0 statistical software. The Shapiro–Wilk test was used to test for normal distribution. Continuous data are expressed as the mean and standard deviation for normally distributed variables, and as the median for non-normally distributed data. Categorical variables are presented as percentages. Continuous variables were analyzed using t-tests or Mann–Whitney U-tests, while categorical variables were analyzed using Pearson's chi-squared test or Fisher's exact test. The least significant difference test was used for statistical analysis of repeated measures of pain scores. All statistical tests were conducted using a two-tailed test with a significance level of 0.05.

3. Results

3.1. Patient screening and baseline characteristics

From 15 May 2024 to June 2024, 129 patients who underwent surgery were enrolled in the study. Out of these, 23 patients were excluded for not meeting the inclusion criteria, and 10 patients declined to participate. The remaining 96 patients were randomly assigned to either the taVNS group ($n = 48$) or the sham stimulation group ($n = 48$). Six patients were subsequently excluded from the study: the anaesthesia method was changed for 3 of the patients (2 in the taVNS group and 1 in the sham stimulation group), and 3 patients cancelled their surgery (1 in the taVNS group and 2 in the sham stimulation group). Therefore, a final total of 90 patients (45 in the taVNS group and 45 in the sham stimulation group) were included in the statistical analysis, as depicted in Figure 1. The baseline values between the two groups indicated no statistically significant differences (Table 1).

3.2. Primary outcome

The VAS score at the first dressing change was significantly lower in the taVNS group compared to the sham stimulation group (3.08 ± 0.54 vs. 4.97 ± 0.47, $p < 0.01$, Table 2).

3.3. Secondary outcomes

The pain scores of patients in both groups gradually increased 24 h postoperatively, with the most severe pain occurring during the first postoperative defecation. The pain scores in the taVNS group were significantly lower than those in the sham stimulation group at 2 h (1.65 ± 0.52 vs. 2.36 ± 0.76, $p < 0.01$), 6 h (3.00 ± 0.38 vs. 3.68 ± 0.57, $p < 0.01$), 24 h (3.15 ± 0.46 vs. 4.12 ± 0.52, $p < 0.01$), 48 h (2.93 ± 0.41 vs. 3.82 ± 0.53, $p < 0.01$), and 72 h (2.18 ± 0.57 vs. 3.05 ± 0.41, $p < 0.01$) postoperatively. The differences were statistically significant. The VAS

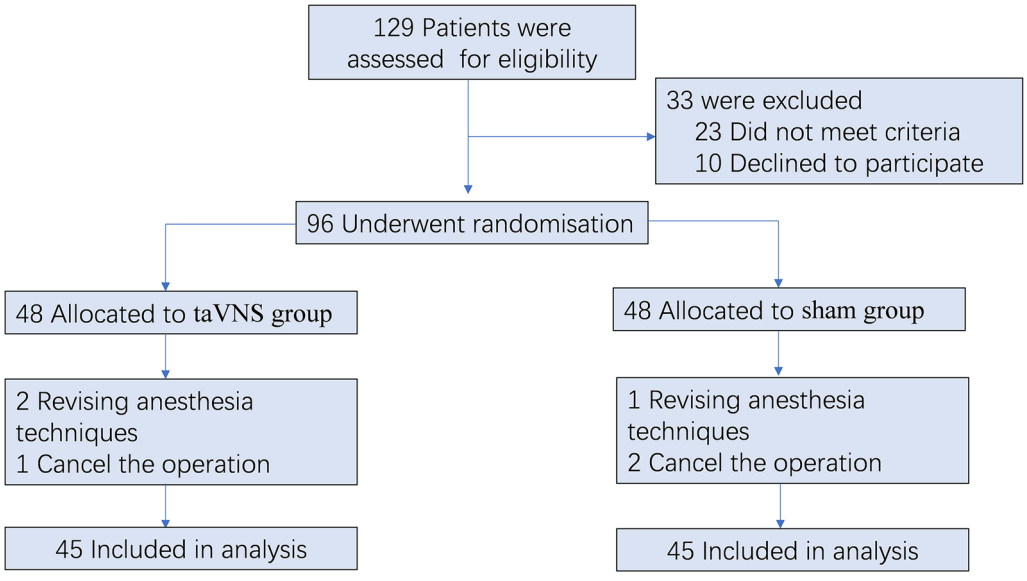

Figure 1. Flow chart of patient enrolment.

score at the first defecation was also significantly lower in the taVNS group compared to the sham stimulation group (3.54 ± 0.76 vs. 5.44 ± 0.82, $p < 0.01$). However, the difference in VAS scores between the two groups at 7 days postoperatively was not statistically significant (1.28 ± 0.49 vs. 1.20 ± 0.58, $p = 0.49$, Table 2).

Compared with the sham stimulation group, the frequency of taking oral paracetamol and tramadol per person per day within 7 days after surgery was lower in the taVNS group (2.51 ± 0.66 vs. 3.42 ± 0.62, $p < 0.01$; 0.29 ± 0.46 vs. 1.18 ± 0.68, $p < 0.01$).

3.4. Other secondary outcomes

The time of the first defecation and the defecation times per day were not statistically significant between the taVNS group and the sham stimulation group (29.09 ± 4.82 vs. 30.31 ± 5.74, $p = 0.44$; 1.22 ± 0.42 vs. 1.36 ± 0.48, $p = 0.17$). Regarding the incidence of perioperative adverse reactions, the incidence of urinary retention was lower in the taVNS group compared to the sham stimulation group ($p = 0.04$). However, the difference in the incidence of nausea and vomiting between the two groups was not statistically significant ($p = 0.75$). Both groups tolerated the intervention stimuli well, with no occurrences of auricular skin burns, itching, headache, hypotension, or bradycardia. The overall satisfaction among patients in the taVNS group was higher than that of the sham stimulation group ($p = 0.02$). Specific data were given in Table 3.

Table 1. Demographic characteristics and baseline values.

Characteristic	taVNS group	Sham group	P value
Age (years)	38.24 ± 11.57	36.6 ± 12.1	$p = 0.48$
Gender (male/female)	21/24	23/22	$p = 0.34$
ASA Class I/II (cases)	20/25	23/22	$p = 0.43$
Surgical procedures			$p = 0.85$
Mixed haemorrhoidectomy	28	26	
Anal fistulectomy	11	12	
Anal fissure excision	3	2	
Perianal abscess incision and drainage	3	5	
	23.34 ± 2.52	22.81 ± 2.78	$p = 0.22$
Surgery time	20.11 ± 5.99	18.96 ± 6.17	$p = 0.36$
Education level			$p = 0.98$
Primary school and below	2	1	
Secondary school	13	15	
Undergraduate	20	18	
Postgraduate and above	10	11	

Gender and education are expressed as the number of people, and BMI, age, and surgery time are expressed as mean ± standard deviation.

4. Discussion

In this study, patients in the taVNS group exhibited lower VAS scores compared to those in the sham stimulation group during the first postoperative dressing change and defecation. Their VAS scores were significantly lower at 2, 6, 24, 48, and 72 h postoperatively. The taVNS group also required fewer analgesics than the sham stimulation group. Furthermore, the incidence of urinary retention was significantly lower in the taVNS group. No significant differences were observed between the two groups concerning other perioperative adverse events. Overall, the analgesic effect of taVNS was superior to that of sham stimulation and was well tolerated by patients, without significant adverse reactions.

Mismanagement of pain during the first postoperative dressing change and defecation presents a significant challenge in the perioperative management of perianal surgery [21]. At our hospital, the first dressing change is conducted by the surgeon 24 h postoperatively. Consequently, selecting the VAS score at the first dressing change as the primary outcome for postoperative pain assessment in this study is clinically significant. Timely defecation after perioperative surgery is crucial for postoperative recovery. However, many patients experience difficulty in defecation due to intense pain and perianal muscle spasm, which exacerbates postoperative pain and creates a vicious cycle. This difficulty can even lead to infection and bleeding [22,23]. The results of this study demonstrate that taVNS can significantly reduce pain during the first defecation and enhances patient satisfaction following perianal surgery. By providing a non-pharmacologic analgesic option, taVNS may serve as a valuable addition to the existing standard of care for patients undergoing perianal surgery. Importantly, the use of taVNS in this study did not result in adverse events like skin burns, itching, headache, hypotension, or bradycardia.

Individual differences in pain thresholds may have some effect on trial results. To reduce this effect, the present study adopted a randomised trial design with blinded subjects, controlling for other confounding factors, and used a recognised VAS rating scale to assess pain to minimise the effect of individual differences. In addition, postoperative analgesia affects VAS

Table 2. Postoperative pain scores (VAS).

VAS	2 h	6 h	24 h	48 h	72 h	7d	Initial dressing change	Initial defecation
taVNS group	1.65 ± 0.52	3.00 ± 0.38	3.15 ± 0.46	2.93 ± 0.41	2.18 ± 0.57	1.28 ± 0.49	3.08 ± 0.54	3.54 ± 0.76
Sham stimulation group	2.36 ± 0.76*	3.68 ± 0.57*	4.12 ± 0.52*	3.82 ± 0.53*	3.05 ± 0.41*	1.20 ± 0.58	4.97 ± 0.47*	5.44 ± 0.82*

Note: *$p < 0.01$.

Table 3. Other secondary outcomes.

	taVNS group	Sham stimulation group	P value
Analgesic drugs (tablets/day)			
Paracetamol	2.51 ± 0.66	3.42 ± 0.62	$p < 0.01$
Tramadol	0.29 ± 0.46	1.18 ± 0.68	$p < 0.01$
Initial defecation time (hours)	29.09 ± 4.82	30.31 ± 5.74	$p = 0.44$
Defecation times per day	1.22 ± 0.42	1.36 ± 0.48	$p = 0.17$
Nausea and vomiting (number of person times)	5	6	$p = 0.75$
Urinary retention (number of person times)	2	8	$p = 0.04$
Satisfaction (satisfied, basically satisfied, not satisfied)	28/11/6	15/16/14	$p = 0.02$

scores, and for ethical reasons, the conventional analgesic regimen, i.e. oral paracetamol and rectal suppositories, was still used in this study in the postoperative period, and remedial analgesia was taken in the form of oral tramadol tablets. Postoperative analgesic measures may mask the effect of auricular vagus nerve stimulation intervention, but the results of this study still show the efficacy of auricular vagus nerve stimulation.

It is noteworthy that besides the surgical procedure itself and anaesthetic medications, pain management can also contribute to short-term complications such as urinary retention following perianal surgery [24]. In our study, the incidence of urinary retention in the sham stimulation group was 17.8%, consistent with previous findings [25]. In contrast, the incidence in the taVNS group was 4%, which may be attributed to lower VAS scores and potential enhancement of bladder function by taVNS to facilitate bladder recovery. Interestingly, there was no statistically significant difference observed between the time to the first defecation and defecation frequency in the taVNS group compared to the sham stimulation group. This indicates that the influence of taVNS on defecation and stool passage formation warrants further investigation and assessment.

In recent years, clinical studies have significantly assessed the analgesic effects of taVNS. Busch et al. demonstrated that taVNS can inhibit injurious sensation and nociceptive conduction processes, thereby raising the nociceptive threshold of the body and decreasing pain sensitivity, while leaving the autonomic nervous system unaffected [26]. Similarly, the latest clinical study conducted by Patel et al. indicated that taVNS reduces acute pain following upper extremity fracture surgery and minimizes autonomic changes, which is advantageous in pain regulation [19]. Despite these advancements, the mechanisms underlying the analgesic effects of taVNS remain underexplored. Busch et al. propose that these effects primarily involve central pain processing, whereas Patel et al. indicate a potential link to autonomic nerve function modulation [19,26]. A study conducted by Zuo et al. indicates that activating the cholinergic anti-inflammatory pathway may be pivotal in the analgesic mechanism of taVNS [27]. In our present study, we observed significant reduction in postoperative pain among patients undergoing perianal surgery with taVNS. However, the precise mechanism of action remains unclear and warrants further investigation in future research.

Limitations of this study include: (1) The study was a single-centre design with a small sample size and included several perianal conditions with different levels of postoperative pain. Further validation of the safety and efficacy of percutaneous auricular vagus nerve stimulation is needed in the future through more rigorous designs and larger sample size; (2) data collection focused solely on VAS scores at rest, omitting assessment during physical activity; (3) the study did not establish minimum thresholds for frequency, duration, intensity, or stimulation parameters of the interventions required for optimal clinical outcomes, necessitating further investigation in subsequent research; (4) The results of this study may not be applicable to patients with a history of previous perianal surgery, a history of psychiatric disorders, and a history of chronic preoperative pain or long-term use of analgesics, as there may be abnormalities in pain perception in these patients; (5) In this study, pain medication consumption was collected from nursing transcripts, which may have underestimated patients' actual need for pain medication; (6) Although ultrasound-guided pubic nerve blocks were used in this study, the efficacy of pubic nerve blocks was not assessed.

5. Conclusion

taVNS provides relief from postoperative pain in patients undergoing perianal surgery, particularly during dressing changes and defecation. It reduces the requirement for postoperative analgesics without increasing the risk of complications. taVNS represents a novel, non-invasive, and cost-effective analgesic intervention with significant potential for clinical application.

Author contributions

CRediT: **Zhi-Yu Yin**: Conceptualization, Formal analysis, Writing – original draft; **Jing Wang**: Formal analysis, Writing – original draft; **Pan Wei**: Data curation, Formal analysis; **Hao Gao**: Formal analysis, Funding acquisition; **Long Sun**: Data curation, Formal analysis; **Jian-Gang Song**: Conceptualization,

Formal analysis, Funding acquisition, Writing – review & editing; **Wei Tang**: Conceptualization, Writing – review & editing.

Clinical registration details

Trial registration: Chinese Clinical Trial Registry, ChiCTR 2400084004.

Register URL link: https://www.chictr.org.cn/

Register date: 2024-05-09

Ethics approval and consent to participate

This study was conducted with approval from the Ethics Committee of Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine (No.2024-1495-078-01). This study was conducted in accordance with the declaration of Helsinki. Written informed consent was obtained from all participants.

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Conception and design of the research: Zhi-Yu Yin, Jian-Gang Song, Wei Tang; Acquisition of data: Pan Wei, Long Sun; Analysis and interpretation of the data: Jing Wang, Hao Gao, Jian-Gang Song; Statistical analysis: Zhi-Yu Yin, Pan Wei, Long Sun; Obtaining financing: Hao Gao, Jian-Gang Song; Writing of the manuscript: Zhi-Yu Yin, Jing Wang; Critical revision of the manuscript for intellectual content: Jian-Gang Song, Wei Tang; All authors read and approved the final draft.

Disclosure statement

No potential conflict of interest was reported by the authors.

Data availability

The datasets used or analysed during the current study are available from the corresponding author on reasonable request.

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