Study Protocol

Evaluation of the efficacy and safety of intradermal needle therapy on the sleep quality of patients following laparoscopic hysterectomy: study protocol for a randomized controlled trial

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Background: Sleep disorder is a commonly reported complication in patients who have undergone a hysterectomy, which increases perioperative complications and delays patient recovery. Several pharmacological and non-pharmacological approaches have been employed to improve the quality of sleep of patients during the postoperative period, but these strategies have certain limitations. Intradermal needle therapy is now among the most common treatments for insomnia in traditional Chinese medicine (TCM). The present study was developed to explore the effects of intradermal needle therapy (as an adjunct to physiotherapy-based treatments for postoperative sleep impairment) on the postoperative sleep quality of patients who have undergone a laparoscopic hysterectomy.

Methods: This is a prospective, single-center, single-blind, randomized controlled trial. In total, 80 eligible patients will be randomly allocated to the control and experimental groups at a 1:1 ratio. Random numbers and grouping schemes will be generated using the SPSS 25.0 software package. Following the completion of the laparoscopic hysterectomy procedure, the patients will be returned to the medical ward and undergo authentic or sham intradermal needle therapy as appropriate. For patients in the experimental group, following sterilization, intradermal needles will be inserted into the bilaterally "Shenmen" (HT36) and "Sanyinjiao" (SP6) acupoints; the needles will be replaced after 24 h. False intradermal needles that exhibit similar surface characteristics but lack needles will be employed in the control group. Patients will undergo a single 3-day treatment course. The primary outcome is the Pittsburgh Sleep Quality Index. The secondary outcomes are the 10-Item Short-Form Identity-Consequence Fatigue Scale, the Hospital Anxiety and Depression Scale—Anxiety, and postoperative pain scores, which will be rated using a visual analog scale. Time to postoperative defecation and the duration of hospitalization will also be recorded.

Discussion: The present study seeks to examine the efficacy of the intradermal needle as a therapeutic tool for improving the sleep quality of patients after surgery who have undergone a laparoscopic hysterectomy to provide a foundation for future large-scale clinical studies.

Trial Registration: Chinese Clinical Trial Registry (identifier: ChiCTR2200056890).

Keywords: Intradermal needle; laparoscopic hysterectomy; postoperative sleep quality; randomized controlled trial (RCT)

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Introduction

Severe postoperative sleep disturbances and concomitant reductions in overall sleep quality are commonly reported by patients who have undergone surgery (1). Polysomnographic studies have detected sleep disturbances, including a reduction of up to 80% in total sleep time (2). In some reports, reduced rapid eye movement sleep, deep sleep, and sleep efficiency have been reported from nights 1–3 postoperatively, resulting in varying levels of sleep disturbance and adversely affecting patients' quality of life (2,3).

Hysterectomies are the 2nd most common major surgical procedure for women; indeed, an estimated 1 in 3 women have undergone this procedure by 65 years of age (4). Insomnia and poor sleep quality are among the most common postoperative complications reported by patients that have undergone a hysterectomy (5). This is problematic given that even limited sleep impairment can lead to negative effects, including fatigue, sleepiness, and a loss of vigor, which can delay recovery and increase perioperative complications (6). A majority of hysterectomy procedures are performed using the laparoscopic approach, and over 60% of patients are estimated to suffer from sleep disorders following laparoscopic hysterectomy (7,8). Thus, further efforts are required to raise awareness about the importance of attaining sufficient sleep following a hysterectomy, and there is a clear need for the development of interventions capable of preventing or remediating postoperative sleep impairment in these patients.

Prophylactic pharmacological interventions are commonly employed in clinical practice, with dexmedetomidine and melatonin being among the most commonly used agents for the prophylactic treatment of perioperative sleep disturbances (1,7,9,10). In a recent meta-analysis, Zhang *et al.* found that dexmedetomidine is associated with higher rates of hypotension and bradycardia in treated patients (11). Additionally, while some experimental evidence suggests that melatonin promotes sleep and shifts circadian cycles in a beneficial manner, such evidence is inconsistent with other findings, and heterogeneity has been reported among studies (12). In China, the Western medicine most commonly used to improve sleep quality is alprazolam, but doses >0.5 mg are often associated with disruptive side effects (13). No definitive, reliable approach for preventing or treating postoperative sleep disturbances has been reported to date.

Due to the limited efficacy of extant pharmacological approaches for treating sleep impairments and the associated adverse side effects, several non-pharmacological interventions have been developed, including foot baths, auricular acupressure, abdominal acupuncture, and aromatherapy, all of which have been reported to have good efficacy (14-17). However, due to a number of factors, including fear of acupuncture, pain, and perioperative bed rest, the implementation of these techniques has been somewhat restricted. In addition, to date, there has been insufficient research on effective perioperative sleep quality management. As such, effective approaches for improving postoperative sleep quality that have the potential to effectively promote efficient patient recovery urgently need to be identified.

Acupuncture is among the most popular form of alternative medicine practiced in Eastern Asia, and it is now practiced in Western countries (18). Extant acupuncture techniques primarily consist of traditional needle-based acupuncture and electroacupuncture. Acupuncture has been used to treat insomnia since ancient times. There are records of relevant contents from the earliest *Huangdi Neijing* to modern medical works. There is a study on the ancient books on acupuncture and moxibustion for insomnia, and believed that the acupuncture and moxibustion prescriptions in the ancient books had a significant impact on insomnia. It has rich clinical experience and is worthy of clinical study (19). However, in our clinical experience, we have found that traditional acupuncture is associated with dizziness, and carries a risk of bent or stagnant needles, as the needle body needs to remain fixed in a single location. Additionally, the acupuncture leads to strong stimulation, many patients have a fear of acupuncture, and as there are many acupoints to choose from, the resultant treatment processes are time-consuming and more medical resources are consumed.

Recent developments in acupuncture techniques have led to the development of hand-pressed intradermal needles, which are shallow needles that do not induce the sensations associated with needle insertion and allow for prolonged (1–7 days) needle retention. As the needle body is short and thin (see *Figure 1*), it is very safe and cannot cause damage to nerves, blood vessels, or internal organs. Intradermal needle therapy, also referred to as intradermal acupuncture therapy, has recently been employed to treat a range of conditions due to its key therapeutic advantages (20-23). The needles are affixed to a waterproof, latex-free, microporous tape that has good air permeability and can be attached to the skin for extended periods during which patients can move without experiencing discomfort. Continuous stimulation is applied to the selected site, thereby ensuring greater efficacy.

Figure 1 Intradermal needles.

Intradermal needle therapy is now among the most common treatments for insomnia in traditional Chinese medicine (TCM). In one study, You found this therapy to be superior to traditional acupuncture as a means of improving sleep quality, sleep duration, daytime function, and associated clinical efficacy in patients suffering from insomnia with liver stagnation and fire syndrome (24). Additionally, Zhang found that the combined application of intradermal needle therapy and 5-tone therapy improved the symptoms of liver-yang hyperactivity type insomnia in hypertensive patients (25). Other analyses on the use of intradermal needle therapy as a treatment for insomnia over the past decade have confirmed that it has a clinical efficacy >90% when deployed in combination with other therapies (26). Such findings emphasize the value of this approach in improving sleep quality.

In light of the above evidence, the present clinical pilot trial was developed to assess the efficacy of intradermal needle therapy as a means of preventing poor postoperative sleep quality in patients undergoing laparoscopic hysterectomy to highlight a new interventional approach for treating perioperative sleep disorders worthy of further study. We present the following article in accordance with the SPIRIT reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2980/rc).

Methods

Study design

The present study is a parallel, single-center, single-blind (patient), prospective, randomized controlled trial (RCT). The enrolled patients will be patients undergoing a laparoscopic hysterectomy at the Department of Gynecology of Guangdong Provincial Hospital of Chinese Medicine between February 2022 and June 2023. The study flow chart is shown in *Figure 2*.

Ethical issues

The study will be conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of the Guangdong Provincial Hospital of Chinese Medicine has approved the present study (No. ZF2022-006-01). All the patients will be required to provide written informed consent before their enrollment in the trial.

Sample size

The present preliminary clinical trial seeks to establish the feasibility of using intradermal needle therapy as a means of improving postoperative sleep quality in patients undergoing laparoscopic hysterectomy. As such, no specific statistical sample size calculations will be made before patient recruitment (27). Instead, an alternative approach was adopted for the sample size estimation of the pilot study, with 10–40 patients being enrolled per group (28). Specifically, we aim to enroll a total of 60 patients (30 per group) in our analyses. Assuming a 20% drop-out rate, we will seek to recruit 80 patients in total (n=40/group).

Case selection

Diagnostic criteria

Western medicine diagnostic criteria

Short-term, chronic, and other forms of insomnia will be diagnosed as per the "Guidelines for the diagnosis and treatment of adult insomnia in China (2017)" (29).

TCM diagnostic criteria

Insomnia will be diagnosed as per the 2016 "Insomnia TCM Clinical Practice Guidelines" standard (30).

Inclusion criteria

Patients undergoing a laparoscopic hysterectomy eligible

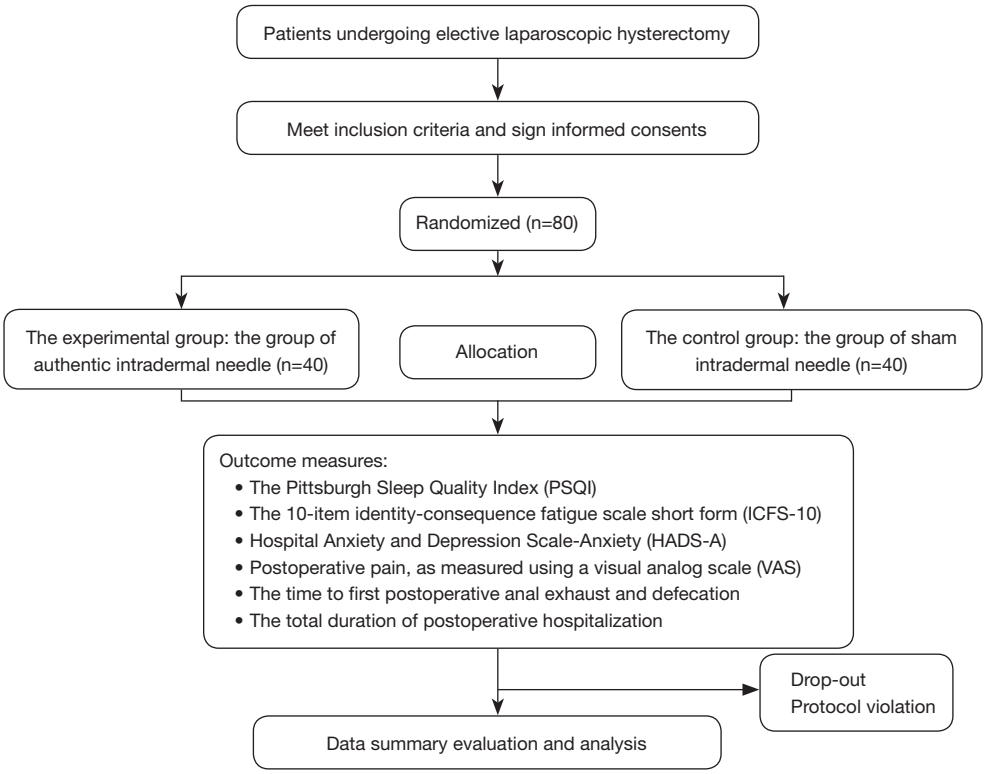

Figure 2 Trial flow chart.

for inclusion will be selected with reference to the "Total Hysterectomy: Surgical Method for Benign Disease" edited by Hua (31). In brief, a patient will be eligible for inclusion in the study if they meet the following inclusion criteria: (I) is a female who has been diagnosed with non-malignant uterine tumors or adnexal masses, or early-stage tumors (including stage IA1 tumors and carcinoma *in situ*) and who meets the surgical indications for laparoscopic total hysterectomy; (II) is aged 18–65 years; (III) has an American Society of Anesthesiologists (ASA) grade of I–II; anesthesia will be achieved via tracheal intubation; the operative duration will be <4 h; the intraoperative blood loss will be <300 mL; (IV) has no history of short-term or chronic insomnia; (V) has no reported preoperative mental health disorders, illnesses, or a history of substance abuse or sedative drug abuse; and (VI) agrees to participate in the study and provides written informed consent.

Exclusion criteria

A patient will be excluded from participating in the present study if they meet any of the following criteria: (I) has a history of sleep disorders, mental health disorders, or sedative drug abuse; (II) has a severe primary or secondary disease affecting major organs, including the brain, kidney, liver, or heart; (III) has local skin wounds, infections, or tape allergies at the target acupoints; (IV) has participated in other clinical trials within the past year; and/or (V) has been diagnosed with diabetes.

Dropout criteria

A patient will be withdrawn from the study if they meet any of the following criteria: (I) fail to meet the selection criteria and has incomplete data sets; (II) does not receive the prescribed treatment; (III) experiences severe complications, adverse reactions, or rapid deterioration during the trial, in which case the trial will be terminated; or (IV) is a patient for whom the researchers believe the testing cannot be successfully completed.

Randomization and allocation concealment

Random numbers and grouping schemes will be generated using the SPSS 25.0 software package. In total, 80 patients will be assigned to either the control or experimental

groups (n=40/group), and will receive sham or authentic intradermal needle therapy, respectively. Envelopes will be used to conceal the grouping scheme, with each envelope containing allocation information and exhibiting a consecutive serial number on the outside. An envelope will be opened when a participant is enrolled in the study after completing the baseline assessments. After assignment to either of the 2 groups, the participants will receive the appropriate intervention.

Blinding

This is a single-blind study in which the patients will be blinded to their group allocation, while the researchers, acupuncturists, and outcome assessors will be aware of these allocations. Those interpreting the study results will also be blinded to minimize the potential for the misleading interpretation of data.

Interventions

All the patients in both the control and experimental groups will receive basic postoperative care consisting of antibiotic treatment, fluid-based rehydration, and appropriate symptomatic treatments, such as dietary guidance, exercise guidance, and psychological care. Patients will not be permitted to use hypnotic or sedative drugs, including Western medicines and TCMs.

Experimental group

In addition to basic care, patients in the experimental group will undergo authentic intradermal needle therapy.

(I) Material preparation: the intradermal needles consist of disposable aseptic pressure needles affixed to waterproof adhesive tape. These needles are smaller and penetrate less deeply than the needles traditionally used in acupunctural contexts and require less manipulation. For this study, Suzhou Huatuo brand disposable press needles (0.25 mm × 1.3 mm; Suzhou Medical Products Factory Co., Ltd.) will be used. Other necessary materials will include tweezers, 75% ethanol, and cotton balls for disinfection.

(II) Acupoints: based on previous research and clinical experience, the Shenmen (HT7) and Sanyinjiao (SP6) acupoints have been selected for therapeutic targeting.

(III) Acupoint positioning and intradermal needle insertion: Needle therapy will be conducted in a manner consistent with the Standardized Manipulations of Acupuncture and Moxibustion-Part 8: Intradermal Needle (GB/T 21709.8-2008) publication (32). Acupoints will be located in accordance with the World Health Organization's (WHO's) Standard Acupuncture Point Locations in the Western Pacific Region (Chinese-English bilingual edition) (33).

(IV) Operative approach: after returning to the ward following the laparoscopic hysterectomy, patients will undergo the intradermal needle treatment. Briefly, the selected acupoints will be identified, and the skin at these sites will be disinfected with a sterile cotton ball. Following the disinfection of the therapist's hands, the skin at the selected acupoint will then be fixed by hand, after which tweezers will be used to apply the intradermal needle directly to the acupoint, with care being taken to avoid the superficial vasculature. The application of the needle should be painless and should not affect patients' activities. Patients will be instructed to press on the tape 3–4 times per day to stimulate the acupoints, pressing each acupoint for 1 min at a time, according to the patient's tolerance; the interval between 2 times should be about 4 h.

When the needle is to be removed, the skin on both sides of the needle will be fixed by hand, after which tweezers will be used for needle extraction. Once per day during the needle retention period, researchers will check to ensure the proper fixation of the tape overlying the needles. In instances where the tape has shifted or fallen off, the needle will be replaced with a new needle. The intradermal needles will thus remain embedded in the patients throughout the duration of the 3-day treatment course, with a single course of treatment being performed followed by needle removal.

Control group

In addition to basic care, patients in the control group will be treated with sham intradermal needles that appear similar to the actual needles on the surface but lack any underlying needles. These sham needles will be attached to the surface of the skin over the target acupoints, with all manipulations and positions being identical to those in the experimental group. The treatment frequency and retention times will also be the same as those in the experimental group. To ensure study homogeneity, qualified therapists trained in the intradermal needle technique before the study initiation

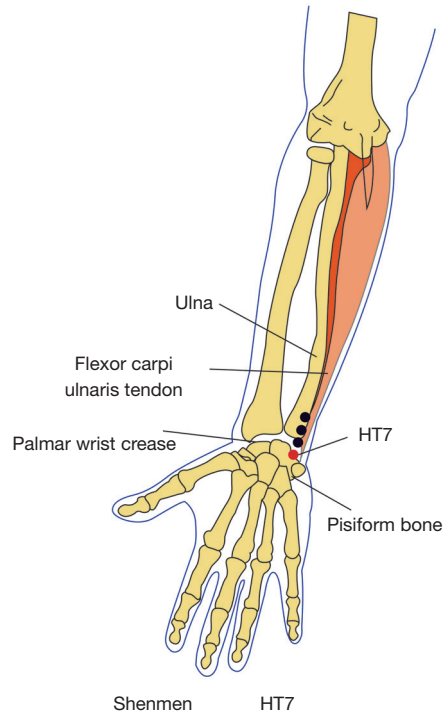

Figure 3 Location of the Shenmen (HT7) acupoint.

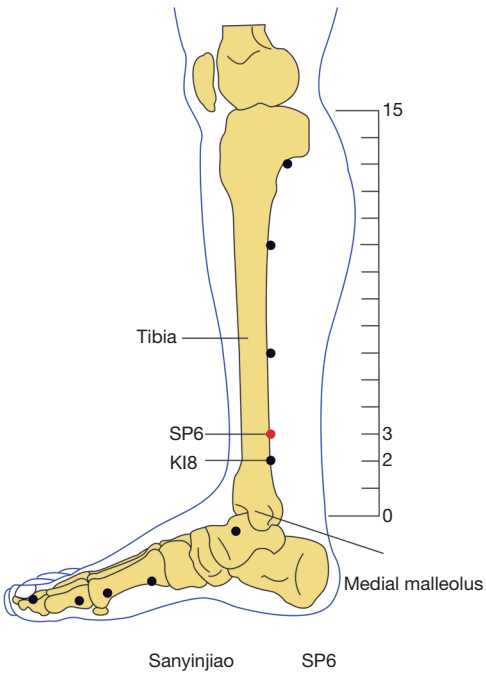

Figure 4 Location of the Sanyinjiao (SP6) acupoint.

will perform all the manipulations in the present study.

Acupoint locations

The HT7 and SP6 acupoints will be located in accordance with standard WHO criteria as follows:

(I) HT7: On the anteromedial aspect of the wrist, radial to the flexor carpi ulnaris tendon, on the palmar wrist crease (see *Figure 3*). Note: In the depression radial to the proximal border of the pisiform bone, on the palmar wrist crease.

(II) SP 6: On the tibial aspect of the leg, posterior to the medial border of the tibia, 3 B-cun superior to the prominence of the medial malleolus (see *Figure 4*). Note: 1B-cun superior to KI8.

Outcome measures

Major outcome measures

The primary outcome measure used for the present study is the Pittsburgh Sleep Quality Index Scale (PSQI), which will be administered 1 day before surgery and on days 1 and 3 postoperatively, with the rate of PSQI score reduction being the primary readout of interest. PSQI score reduction rates, which will be used to monitor overall curative efficacy, will be calculated using the following nimodipine formula: PSQI score reduction rate = (total score before treatment – total score after treatment)/total score before treatment × 100%. The total effective rate is defined as the recovery rate + the significantly effective rate + effective rate (34), where, the recovery rate refers to a score reduction rate ≥90%; the significantly effective rate refers to a score reduction rate ≥60% and ≤90%; the effective rate refers to a score reduction rate ≥30% and ≤60%; and an invalid rate refers to a score reduction rate <30%.

Secondary outcome measures

The secondary outcome measures in this study are the:

(I) 10-Item Identity-Consequence Fatigue Scale Short Form (ICFS-10), which will be administered on the day of surgery and on days 1 and 3 post-surgery;

(II) Hospital Anxiety and Depression Scale-Anxiety (HADS-A), which will be administered on the day of surgery and on days 1 and 3 post-surgery;

(III) Postoperative pain, as measured using a visual analog scale (VAS) on the day of surgery and on days 1 and 3 post-surgery;
(IV) The time to first postoperative anal exhaust and defecation;
(V) The total duration of postoperative hospitalization.

Basic characteristic variables

The basic characteristic variables are as follows:

(I) Patient age, operative approach, operative duration, analgesic pump use, intraoperative blood loss, and other details;
(II) Vital signs, including pulse, body temperature, respiration rate, and blood pressure at rest, which will be measured by nursing staff on a daily basis; and
(III) Safety indicators, including routine blood parameters, liver function tests, and kidney function tests, which will be assessed before and after surgery.

Statistical analysis

Statistical analyses will be conducted using SPSS 25.0 by statisticians, with the primary analyses entailing the comparison of outcome measures within and between groups to assess the effects of the intradermal needle treatment. In addition, the actual sample size is larger than our target sample size, so if a case exits, resulting in missing data, we will directly discard the missing data. In this study:

(I) If the measurement data are normally distributed, they will be expressed as the mean ± standard deviation, but they will otherwise be expressed as the median (P25, P75).
(II) *T*-tests will be used for comparisons between groups for data that are normally distributed and exhibit homogeneity of variance; otherwise, Mann-Whitney tests will be used.
(III) Paired *t*-tests will be used when the assumptions of homogeneity of variance and normality are met to compare the pre- and post-treatment data; otherwise, the data will be compared using Wilcoxon signed-rank tests.
(IV) For graded data, the number of cases will first be weighted, after which the rank-sum tests or non-parametric tests will be used for the analyses.
(V) Counting data will be analyzed using chi-squared tests.

A 2-sided P value <0.05 will be the threshold of significance for all the analyses in the present study.

Quality control

All researchers will be trained before study initiation in the research process, rule implementation, inclusion/exclusion criteria, the treatment regimen, acupoint selection and acupuncture techniques, data collection and management, monitoring of curative effects, and adverse event reporting and recording. The trial will be terminated in any of the following instances: (I) if a patient experiences severe complications, adverse events, or deterioration leading a doctor to conclude that the study should be stopped; (II) if a patient becomes reluctant to continue to participate in the study and wishes to drop out; or (III) if special physiological changes occur in the body during the study period, and it is not appropriate to continue the study.

Adverse event recording and handling

In addition to assessing the potential curative outcomes, the researchers will monitor the patients for adverse reactions. In cases in which adverse events or reactions are observed, the occurrence time, signs, symptoms, duration, treatment approach, and outcomes will be recorded in detail irrespective of the correlations between the treatment and the adverse events. Necessary treatments will be provided to patients experiencing adverse events to ensure they enter into a stable condition. All the adverse events, including pain, hematoma, acupuncture site infections, and syncope, will be treated using conventional methods associated with acupuncture accidents.

Discussion

Hysterectomy is among the most frequently performed non-obstetric procedures; an estimated 430,000 hysterectomies are conducted in the United States annually, of which >80% are performed to treat benign diseases, including endometriosis, pelvic organ prolapse, abnormal uterine bleeding, and leiomyoma (35,36). Minimally invasive surgical approaches are becoming increasingly common, and account for upwards of 93% of all surgeries (36). Laparoscopic hysterectomies are minimally invasive and entail reductions in hospitalization duration, blood loss, and postoperative pain, but they have a number of disadvantages, including a longer operative duration than that required for the traditional abdominal approach, which is noteworthy given

that operative prolongation has been linked to adverse outcomes irrespective of the surgical approach (37). Further, in addition to inducing negative postoperative reactions, such as sleep disorders, changes in body positioning and the need to establish artificial pneumoperitoneum during the laparoscopic procedure can alter respiratory function and cardiac output (7). Kjølhede *et al.* noted that sleep quality is essential to postoperative recovery after gynecological surgery (6). As such, efforts to improve sleep quality are important to optimize postoperative recovery in fast-track programs; however, very few programs include specific strategies for postoperative sleep improvement (38). Recently, Krenk *et al.* posited that fast-track methodologies should incorporate prophylactic strategies to ameliorate the sleep architecture (39).

A number of negative outcomes are associated with reduced postoperative sleep quality, including cognitive impairment, mood disturbances, delirium, metabolic dysregulation, inflammation, fatigue, altered pain perception, and sleep disturbances (40). Thus, improving the perioperative sleep quality of patients undergoing surgery can improve patient outcomes and reduce the incidence of adverse events. At present, both pharmacological and non-pharmacological approaches to improving sleep quality are limited in terms of efficacy. Thus, we seek to identify a safe and effective approach for combatting postoperative sleep disturbances that is associated with fewer adverse events and is accepted by patients, as such an approach would be clinically significant and may aid in expediting the recovery of treated patients.

Intradermal needle therapy has a number of clinical advantages that make it attractive, including the fact that it is associated with low levels of pain, few adverse reactions, and satisfactory outcomes (41). Intradermal needles are shorter and easier to operate than traditional acupuncture needles. Such needles can induce a piercing sensation, but this sensation is generally likened to a slight tingling, and the needles can remain in place for 24 h, which prolongs the efficacy of acupuncture. In addition, they can be operated by trained nursing staff and readily administered. Following surgical trauma and associated postoperative stress, the nervous system is generally in a state of increased excitement and activity. Cutaneous nerves can transmit signals from the site of needle insertion to the brain upon acupoint stimulation, inhibiting pathological excitation via central regulatory action to alleviate insomnia and other debilitating conditions.

Intradermal needle-based therapeutic approaches combine acupoint and skin theory. Following its placement under the skin, a needle can provide continuous steady stimulation, thereby promoting sustained circulation of qi and blood in the body's meridians, leading to more positive outcomes conducive to overcoming disease or other adverse states. The Shenmen (HT7) and Sanyinjiao (SP6) acupoints are among the sites most commonly employed to treat insomnia (42,43). TCM theory posits that in addition to promoting mental tranquility, which is beneficial to sleep, HT7 is the originating site of the heart meridian and can nourish heart zang. Moreover, SP6 is associated with the spleen channel at the intersection of the spleen, kidney, and liver channels, and coordinates and reinforces the blood and qi to nourish heart zang and sooths the nerves to enhance sleep quality.

As such, we developed the present RCT to examine whether the placement of intradermal needles at the Shenmen and Sanyinjiao acupoints would improve postoperative sleep in individuals undergoing laparoscopic hysterectomy. The results of this study have the potential to aid in the postoperative rehabilitation of patients undergoing surgical procedures. To date, no study has focused on this form of treatment in this patient population, and our data will thus provide insights into the efficacy of this approach and a more robust foundation for future research.

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Footnote

Reporting Checklist: The authors have completed the SPIRIT reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-2980/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.amegroups.com/article/view/10.21037/atm-22-2980/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study will be

conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Ethics Committee of the Guangdong Provincial Hospital of Chinese Medicine has approved the present study (No. ZF2022-006-01). All the patients will be required to provide written informed consent before their enrollment in the trial.

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