STUDY PROTOCOL

Effects of Preoperative Stellate Ganglion Block and Intraoperative Dexmedetomidine on Postoperative Sleep Quality in Patients Undergoing Laparoscopic Gynecologic Surgery: A Randomized, Controlled, 2×2 Factorial Trial

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1. Scientific Rationale and Significance of the Study

1.1 Overview and Development Trends of Research in China and Abroad

In the field of postoperative sleep-quality research, investigators in China and abroad have conducted multidimensional studies on sleep characteristics, influencing factors, and interventions in patients undergoing laparoscopic gynecologic surgery.

International research in this field began relatively early. In patients undergoing laparoscopic gynecologic surgery, multiple studies have demonstrated a high incidence of postoperative sleep disturbance, which is closely associated with surgical trauma, pain, the stress response, and opioid use. With regard to interventions,

international research on dexmedetomidine has been relatively extensive, showing beneficial effects on postoperative sleep architecture and the frequency of nocturnal awakenings. The potential of stellate ganglion block to regulate autonomic function and alleviate postoperative discomfort has also attracted attention; however, studies evaluating the combined use of these two interventions to improve postoperative sleep in patients undergoing laparoscopic gynecologic surgery remain limited.

Research in China has developed rapidly in recent years. Building on international findings while taking local clinical characteristics into account, Chinese investigators have conducted a series of studies. Domestic studies have confirmed that reduced postoperative sleep quality is common after gynecologic procedures such as laparoscopic hysterectomy and have extensively explored the clinical application of dexmedetomidine, clarifying its effects on postoperative sleep at different doses and administration times. Meanwhile, research on the clinical application of stellate ganglion block has also increased, with studies reporting significant effects on postoperative pain relief and modulation of the stress response. Overall, however, most domestic studies have focused on the effects of a single intervention, with relatively limited investigation of the synergistic effects and underlying mechanisms of combined interventions. In addition, some domestic studies remain limited in methodological rigor and sample size compared with certain international studies.

Despite progress in both domestic and international research, several limitations remain. First, the specific mechanisms underlying postoperative sleep disturbance after laparoscopic hysterectomy have not been sufficiently elucidated, particularly the pathways through which surgical trauma, pneumoperitoneum, and related factors influence sleep via the neuroendocrine-immune network. Second, studies of combined interventions are scarce; existing work has largely focused on individual drugs or techniques, with insufficient systematic evaluation of the synergistic effects, optimal combinations, and target populations of multimodal interventions. Third, long-term effects have received limited attention, as most studies assess only short-term postoperative sleep quality, with relatively little investigation of long-term quality of life, psychological health, and other recovery outcomes.

Future research in this field is expected to develop in several directions. First, research may move from mechanistic investigation toward precision intervention by elucidating the molecular mechanisms of postoperative sleep disturbance after laparoscopic hysterectomy and identifying more targeted therapeutic strategies. Second, greater emphasis will likely be placed on multimodal combined interventions to determine optimal combinations of drugs and techniques and to maximize potential synergistic effects on postoperative sleep quality. Third, long-term follow-up should be strengthened so that studies assess not only short-term improvements in sleep but also longer-term recovery, thereby providing evidence for comprehensive postoperative management strategies. Fourth, emerging technologies such as artificial intelligence and wearable devices may enable real-time monitoring and individualized intervention for postoperative sleep quality, improving both research precision and clinical applicability.

1.2 Rationale for the Project

1.2.1 Postoperative sleep disturbance is a common complication of gynecologic surgery, including hysterectomy

Hysterectomy is the second most common surgical procedure among women, after cesarean delivery, and its clinical indications continue to expand. Uterine fibroids, abnormal uterine bleeding, and endometriosis are the three most common indications, and approximately 78.3% of hysterectomies are performed in women younger than 55 years. The surgical approach is selected according to disease characteristics and individual patient factors and mainly includes abdominal, vaginal, and minimally invasive laparoscopic approaches.

Data indicate that between 2008 and 2018, the proportion of total vaginal hysterectomies decreased from 51% to 13%, whereas the proportion of total laparoscopic hysterectomies increased from 12% to 68%. Although laparoscopic surgery may require a longer operative time, its complication rate is significantly lower than that of conventional approaches, and it has gradually become a preferred mainstream surgical technique. Postoperative sleep disturbance is a common complication following hysterectomy, and its impact on patient recovery should not be overlooked.

Postoperative sleep disturbance may adversely affect emotional status, reduce vitality, and increase subjective sleepiness and fatigue, thereby becoming an important factor influencing postoperative recovery. It therefore warrants particular attention within enhanced recovery programs. Under the principles of Enhanced Recovery After Surgery (ERAS), optimizing anesthetic regimens, implementing multimodal analgesia to reduce postoperative opioid consumption, and taking targeted measures to minimize sleep-disrupting factors are important strategies for improving postoperative sleep quality.

1.2.2 Stellate ganglion block (SGB) may be an effective approach for improving postoperative sleep quality

Stellate ganglion block (SGB) is an established clinical technique that has been used safely for more than 80 years. Since the 1940s, its indications have gradually expanded beyond conventional anesthetic applications, and beneficial effects have been reported in pain management, immune-related disorders, sleep disturbances, psychological disorders, arrhythmias, and as an adjunctive treatment for endocrine diseases.

Recent studies have provided supportive evidence for the use of stellate ganglion block (SGB) in sleep-related conditions. Preoperative SGB has been reported to alleviate hot flashes and improve sleep dysfunction in breast cancer survivors, with only mild or no apparent adverse effects. A study by Rui-zhi Yang et al. further demonstrated that preoperative SGB can improve postoperative sleep quality and enhance analgesia in patients undergoing breast cancer surgery.

The perioperative value of stellate ganglion block (SGB) has also been supported by research in other surgical populations. For example, in patients undergoing video-assisted thoracoscopic partial lung resection, preoperative SGB has been shown to attenuate intraoperative visceral stress responses, reduce perioperative opioid consumption, and decrease visceral pain within 24 hours after surgery.

These findings suggest that stellate ganglion block (SGB) may represent a safe and practical intervention for improving postoperative quality of life. Mechanistically, the stellate ganglion is an important component of the sympathetic chain, and its blockade may modulate sympathetic tone and influence the neuroendocrine-immune network, thereby potentially improving the physiological stress state and sleep-regulatory mechanisms. At present, evidence regarding the use of SGB in patients undergoing laparoscopic gynecologic surgery remains limited, particularly with respect to the specific effects and mechanisms of preoperative SGB on postoperative sleep quality in this population. Given the high incidence of postoperative sleep disturbance after laparoscopic gynecologic surgery and the potential value of SGB in sleep improvement and

perioperative management, investigating whether preoperative SGB can improve postoperative sleep quality in these patients has important clinical research significance.

1.2.3 Limitations remain in research on dexmedetomidine (DEX) for postoperative sleep quality

Dexmedetomidine (DEX), a highly selective α2-adrenergic receptor agonist, has attracted considerable attention for its perioperative applications. In addition to providing sedation and analgesia, DEX can reduce the incidence of postoperative delirium and has shown promising potential for improving sleep quality.

Mechanistically, animal studies have provided important evidence regarding the molecular basis by which DEX modulates sleep. Orally administered DEX can decrease c-Fos expression in the cerebral cortex and subcortical arousal systems while increasing c-Fos expression in neurons of the ventrolateral preoptic nucleus, suggesting that it may promote non-rapid eye movement (NREM) sleep in mice by activating sleep-promoting nuclei and suppressing arousal-related nuclei. Nelson et al. further demonstrated that DEX induces sedation through endogenous sleep pathways by inhibiting activity in the locus coeruleus, thereby disinhibiting the ventrolateral preoptic nucleus and promoting γ-aminobutyric acid (GABA) release, which subsequently suppresses firing in the tuberomammillary nucleus and contributes to regulation of the sleep-wake cycle.

At the clinical level, the sleep-improving effects of DEX have been demonstrated in several settings. In non-mechanically ventilated postoperative patients admitted to the intensive care unit, nocturnal DEX infusion may help maintain normal circadian rhythms and optimize sleep architecture and sleep quality. Low-dose DEX infusion (0.1 μg/kg/h) has also been reported to significantly improve postoperative sleep quality in this population, suggesting potential value in the prevention and treatment of postoperative sleep disturbance. Beyond intensive care settings, DEX is widely used for intraoperative sedation, although its effect on postoperative sleep quality remains controversial. Recent studies have shown no significant improvement in postoperative sleep quality among patients undergoing breast cancer surgery, whereas intraoperative DEX has significantly improved postoperative sleep quality in patients undergoing gastrointestinal surgery. Another recent study reported that continuous intraoperative DEX infusion in patients undergoing video-assisted thoracoscopic partial lung resection improved first-night postoperative sleep quality by promoting melatonin secretion during the first two postoperative nights.

Based on the available evidence, the potential mechanisms by which dexmedetomidine improves postoperative sleep quality may involve three principal pathways. First, the sedative effects of dexmedetomidine may act synergistically with endogenous sleep-promoting pathways; studies indicate that it can induce a behavioral state resembling restorative sleep and regulate sleep through activation of specific neuronal populations in the preoptic hypothalamus. Second, dexmedetomidine has an opioid-sparing effect, such as reducing sufentanil requirements, whereas opioids themselves may adversely affect postoperative sleep. Third, DEX may attenuate postoperative inflammatory responses, and inflammation is considered an important risk factor for sleep disturbance.

Although the association between dexmedetomidine and postoperative sleep has been explored, important limitations remain, and the mechanisms underlying differences in its effects across surgical procedures have not yet been clarified. Therefore, further investigation of perioperative DEX administration, particularly intraoperative intravenous administration, on postoperative sleep quality in patients undergoing laparoscopic gynecologic surgery, as well as its relationships with circadian rhythms, inflammatory responses, and other pathophysiological processes, may not only improve the theoretical understanding of DEX-mediated sleep regulation but also provide clinically relevant evidence for optimizing perioperative management and promoting postoperative recovery in this population.

2. Study Objectives

This study aims to investigate the effects of preoperative stellate ganglion block and intraoperative intravenous dexmedetomidine on postoperative sleep disturbance in patients undergoing laparoscopic gynecologic surgery, with the goals of reducing pain and postoperative adverse reactions and identifying an effective, safe, economical, and broadly applicable intervention strategy that may facilitate emergence from anesthesia, accelerate postoperative recovery, shorten the length of hospital stay, and reduce hospitalization costs.

3. Study Overview

This is a single-center, randomized, controlled, 2×2 factorial trial.

3.1 Overall Study Design and Plan

3.2 Study Population

3.2.1 Inclusion Criteria

(1) Patients with American Society of Anesthesiologists (ASA) physical status I–III;

(2) Age 18–75 years;

(3) Scheduled to undergo laparoscopic gynecologic surgery (laparoscopic hysterectomy or laparoscopic surgery for uterine fibroids).

3.2.2 Exclusion Criteria

(1) Preoperative sore throat or hoarseness;

(2) History of upper respiratory tract infection within the previous 2 weeks;

(3) Anticipated difficult tracheal intubation (Mallampati class III or IV, potential facial deformity, mouth opening <3 finger breadths, etc.);

(4) Severe preoperative cardiac, hepatic, renal, or other organ dysfunction;

(5) Allergy to the local anesthetic used in the study, infection at the puncture site, or coagulation abnormalities;

(6) Cognitive impairment, hearing impairment, language impairment, a history of psychiatric illness, or difficulty communicating or cooperating because of a psychiatric disorder.

3.3 Randomization and Blinding

This study uses a single-center, randomized, controlled, 2×2 factorial design. Eligible patients are randomly assigned in a 1:1:1:1 ratio to the stellate ganglion block plus dexmedetomidine group (SD group), stellate ganglion block group (S group), dexmedetomidine group (D group), or control group (C group). The random allocation sequence is generated using a random-number table by an independent researcher who is not involved in patient recruitment, anesthetic management, outcome assessment, data collection, or statistical analysis. Allocation concealment is achieved using sequentially numbered, opaque, sealed envelopes. The corresponding envelope is opened only after patient enrollment, and the intervention is then determined according to the assigned allocation.

Because this study includes two intervention factors, SGB and DEX, blinding procedures are implemented separately. For SGB, because true SGB and sham block differ with respect to needle puncture and drug injection, the anesthesiologist performing the SGB or sham procedure cannot be blinded. However, this anesthesiologist does not participate in postoperative follow-up, outcome assessment, data management, or statistical analysis. To maintain patient blinding, patients in the sham-block group are positioned identically to those in the SGB group, and the ultrasound probe is placed in the same manner on the neck to simulate the procedure, without needle puncture or drug injection. Because both SGB and sham procedures are performed

after induction of anesthesia, patients remain unaware of which procedure they received during perioperative observation.

For DEX, dexmedetomidine or an equal volume of 0.9% sodium chloride solution is prepared according to the randomization scheme by a researcher who is not involved in postoperative follow-up, outcome assessment, or statistical analysis. The study solutions are placed in identical syringes and infusion devices. The intraoperative anesthesiologist administers the study solution according to the predefined infusion protocol and remains unaware of whether the solution contains dexmedetomidine or 0.9% sodium chloride unless unblinding is required for patient safety.

Postoperative SMHSQ scores and Fitbit Charge 6 sleep data are collected and organized by researchers who are blinded to group allocation. Coded group labels are used during statistical analysis, and unblinding occurs only after completion of the primary statistical analyses.

3.4 Sample Size

The sample-size calculation was based on postoperative SMHSQ scores reported in a previous randomized controlled trial. In that study, the SMHSQ scores on postoperative day 1 were 30.88 ± 2.44 in the SGB group and 27.35 ± 4.12 in the control group. Based on comparison of two independent means, with a two-sided α of 0.05 and statistical power of 90%, at least 20 patients were required per group. Allowing for an approximately 10% dropout rate, at least 23 patients were required per group. Considering the 2×2 factorial design and equal allocation across four groups in the present study, the final target sample size was set at 25 patients per group, for a total of 100 patients.

3.5 SGB Procedure

Stellate ganglion block is performed 15 min after induction of anesthesia by an anesthesiologist experienced in ultrasound-guided regional anesthesia, who is aware of the patient's group assignment. The patient is placed in the supine position with the neck slightly extended and rotated to the contralateral side. Under sterile conditions, a high-frequency linear-array ultrasound transducer is used to scan the anterior neck transversely at the C6 level, sequentially identifying the common carotid artery, internal jugular vein, thyroid gland, esophagus, C6 transverse process and anterior tubercle, longus colli muscle, and surrounding vascular structures. In the SGB group, an in-plane needle approach is used under real-time ultrasound guidance. After the needle tip reaches the fascial plane anterior to the longus colli muscle and negative aspiration for blood is confirmed, 5 mL of 0.375% ropivacaine is injected slowly. Spread of the local anesthetic along the surface of the longus colli muscle is observed ultrasonographically to confirm satisfactory distribution. Patients in the sham-block group are placed in the same position and undergo identical ultrasound-probe placement; the probe is applied to the neck to simulate the procedure, but no needle puncture or drug injection is performed. Patients are blinded to group allocation. In the post-anesthesia care unit (PACU), the presence of ipsilateral Horner syndrome is observed and recorded, including ptosis, miosis, facial flushing, or anhidrosis.

3.6 Dexmedetomidine Administration Protocol

According to randomization, patients in the SD and D groups receive dexmedetomidine, whereas patients in the S and control groups receive an equal volume of 0.9% sodium chloride solution. Dexmedetomidine is administered by intravenous infusion after induction of anesthesia without a loading dose, at a rate of 0.2–0.4 $\mu g \cdot kg^{-1} \cdot h^{-1}$, and is continued until the end of surgery. This regimen is based on previous dose-stratified research suggesting that low-dose intraoperative dexmedetomidine (0.2–0.4 $\mu g \cdot kg^{-1} \cdot h^{-1}$) may be more advantageous than moderate or high doses for reducing the incidence of severe postoperative sleep disturbance. MAP, HR, and BIS are routinely monitored during administration. If MAP decreases by >20% from baseline, vasopressor therapy is administered. If HR decreases by >20% from baseline or clinically

significant bradycardia occurs, atropine is administered, and the dexmedetomidine infusion rate is adjusted as appropriate.

4. Anesthetic Management

After arrival in the operating room, peripheral intravenous access is established and balanced crystalloid solution is infused continuously. Electrocardiography, invasive blood pressure, peripheral oxygen saturation, and BIS are monitored routinely. General anesthesia is induced with ciprofol 0.4 $mg \cdot kg^{-1}$, sufentanil 0.5 $mg \cdot kg^{-1}$, and rocuronium 0.6 $mg \cdot kg^{-1}$. A standard fast-track induction is performed. After 5 min of denitrogenation with oxygen, tracheal intubation is performed, and controlled ventilation with 100% oxygen at 2.0 L/min is initiated. Ventilator settings are as follows: tidal volume 8–10 mL/kg, inspiratory-to-expiratory ratio 1:2, with $PETCO_2$ maintained at 35–40 mmHg. During maintenance of anesthesia, all groups receive intravenous remifentanil at 0.1 $\mu g \cdot kg^{-1} \cdot min^{-1}$, ciprofol at 0.4–0.6 $mg \cdot kg^{-1} \cdot h^{-1}$, and rocuronium 0.15 mg/kg as required by the surgical procedure. BIS is maintained between 40 and 60, and mean arterial pressure (MAP) and heart rate are maintained within approximately 20% of baseline values.

At the end of surgery, all anesthetic infusions are discontinued. After extubation, patients are transferred to the post-anesthesia care unit (PACU) for continuous monitoring and the first follow-up assessment, including evaluation for Horner syndrome (facial flushing, enophthalmos, ptosis, miosis, and conjunctival injection) and adverse events. If the VAS pain score in the PACU exceeds 4, oxycodone (5 mg) is administered as rescue analgesia. During the first 48 h after surgery, patients receive patient-controlled analgesia (PCA) consisting of nalbuphine 2 $mg \cdot kg^{-1}$ and dolasetron 0.3 $mg \cdot kg^{-1}$.

5. Outcomes

The primary outcome is perioperative sleep quality, including subjective sleep quality and objective sleep parameters. Baseline sleep quality is assessed 1 day before surgery using the Pittsburgh Sleep Quality Index (PSQI). Subjective sleep quality is evaluated using the St. Mary's Hospital Sleep Questionnaire (SMHSQ) 1 day before surgery, on the day of surgery, and 1 day after surgery. SMHSQ scores range from 11 to 37, with higher scores indicating poorer sleep quality.

Objective sleep parameters are monitored continuously for 3 days using a Fitbit Charge 6 wrist-worn device, namely 1 day before surgery, postoperative day 1, and postoperative day 2. The principal parameters recorded are total sleep time (TST), wake after sleep onset (WASO), and sleep efficiency (SE).

Secondary outcomes include postoperative pain intensity, perioperative opioid consumption, and perioperative safety indicators. Total intraoperative doses of sufentanil and remifentanil and the use of rescue analgesia are recorded. Postoperative pain intensity is assessed using the visual analog scale (VAS) at 6, 24, and 48 h after surgery.

Other observational outcomes include intraoperative hemodynamic variables, Horner syndrome, postoperative length of stay, total hospitalization costs, and perioperative adverse outcomes. Adverse outcomes include complications related to the SGB procedure, such as local anesthetic systemic toxicity, puncture-site hematoma, puncture-site infection, unintended nerve block, and pneumothorax; DEX-related complications, such as bradycardia, hypotension, and hypoxemia; and other postoperative adverse outcomes, including nausea and vomiting, headache or dizziness, nightmares, and excessive dreaming.

6. Adverse Event Monitoring

6.1 Definition of Adverse Events

6.1.1 Definitions

Adverse event: any untoward medical occurrence in a patient or clinical-trial participant after administration of a medicinal product, which does not necessarily have a causal relationship with the treatment.

Serious adverse event: an event occurring during the clinical trial that requires hospitalization or prolongation of hospitalization, results in disability or impaired ability to work, is life-threatening or fatal, or results in congenital abnormality.

6.1.2 Severity

Mild: tolerable to the participant, does not interfere with treatment, requires no special management, and has no effect on recovery.

Moderate: difficult for the participant to tolerate, requires specific management, and has a direct effect on recovery.

Severe: life-threatening, fatal, or disabling, and requires immediate emergency management.

6.2 Recording and Reporting of Adverse Events

Clinical adverse events may occur during treatment. If an adverse event, including an important adverse event, occurs, the time of onset, clinical manifestations, management and duration, outcome, and relationship to the study drug must be documented in detail in the case report form. In the event of an abnormal laboratory result, the participant should be followed until the result returns to normal or to the pre-treatment level, or until the abnormality is determined to be unrelated to the study drug. Any serious adverse event must be documented on the serious adverse event form and reported within 24 hours to the sponsor, the ethics committee, the relevant CFDA safety supervision authority, and the health administrative authority.

6.3 Risk Prevention and Management

6.4 Risk prevention: Extensive literature review will be conducted to ensure that drug dosing is evidence-based. Investigators will be familiar with potential adverse drug reactions to facilitate early recognition.

6.5 Risk management: Appropriate antagonists, rescue medications, and emergency measures will be prepared in advance so that any identified event can be managed promptly.

Statistical Analysis

Statistical analyses will be performed using SPSS version 26.0, and GraphPad Prism version 9.0 will be used for graphical presentation. The normality of continuous variables will be assessed using the Shapiro-Wilk test. Normally distributed continuous variables will be presented as mean ± standard deviation and compared across the four groups using one-way analysis of variance. Non-normally distributed continuous variables will be presented as median (interquartile range) and compared across groups using the Kruskal-Wallis H test. Categorical variables will be presented as number (percentage) and compared using the χ^2 test or Fisher's exact test.

Repeated-measures data, including SMHSQ scores, TST, WASO, SE, and perioperative hemodynamic variables, will be analyzed using generalized estimating equations (GEE). The model will include group, time, and the group × time interaction to evaluate overall differences in temporal patterns among the intervention groups. For statistically significant overall effects or between-group differences at individual time points, Bonferroni-adjusted post hoc pairwise comparisons will be performed, and estimated differences with 95% confidence intervals will be reported.

Given the 2×2 factorial design, receipt of stellate ganglion block and receipt of dexmedetomidine will additionally be entered as two fixed factors to evaluate the main effect of SGB, the main effect of DEX, and the SGB × DEX interaction. When necessary, time will be incorporated into the model to evaluate SGB ×

time, DEX × time, and SGB × DEX × time interactions. All tests will be two-sided, and $P<0.05$ will be considered statistically significant.

6. Ethical Considerations Related to the Study

6.1 Ethics Committee Review

This protocol, the written informed consent form, and all materials directly related to study participants must be submitted to the ethics committee, and the study may commence only after written approval has been obtained. The investigator must submit an annual study report to the ethics committee at least once per year, where applicable. Upon suspension and/or completion of the study, the investigator must notify the ethics committee in writing. The investigator must promptly report all changes occurring during the study, such as amendments to the protocol and/or informed consent form, and such changes must not be implemented before ethics-committee approval unless they are necessary to eliminate an apparent and immediate risk to participants. In such circumstances, the ethics committee will be notified.

6.2 Informed Consent

6.2.1 Procedure for Obtaining Informed Consent

The investigator must provide each participant or the participant's legally authorized representative with an understandable informed consent form that has been approved by the ethics committee and allow sufficient time to consider participation in the study. No participant may be enrolled before written informed consent has been signed. During study participation, participants will be provided with all updated versions of the informed consent form and relevant written information. The informed consent form will be retained as an essential clinical-trial document for future reference.

7. Confidentiality Measures

The results of this study may be published in medical journals; however, patient information will be kept confidential in accordance with applicable legal requirements. Personal information will not be disclosed unless required by law. When necessary, authorized governmental regulatory authorities, the hospital ethics committee, and other relevant personnel may review patient records in accordance with applicable regulations.

8. Expected Study Timeline and Completion Date

2026.10–2026.11: Refine experimental techniques and conduct pilot testing.

2026.11–2026.02: Conduct the formal study.

2026.02–2027.06: Analyze data, draw conclusions, prepare the manuscript, and publish the findings.

9. Main References

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