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Effect of stellate ganglion block on delirium after major surgery in elderly patients: protocol for a randomised controlled study

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ABSTRACT

Introduction Postoperative delirium (POD) remains a prevalent neurological complication among elderly patients following major surgeries, with limited effective preventive measures currently available. Stellate ganglion block (SGB) is widely employed in clinical practices to manage various conditions by modulating the sympathetic nervous system activity. However, there is currently a lack of clinical evidence assessing its effect on the incidence of POD. This study aims to evaluate the safety and efficacy of SGB as a preventive strategy for POD in elderly patients undergoing major surgeries.

Methods and analysis This randomised controlled clinical trial will be conducted at two centres, enrolling a total of 300 elderly patients aged 65 years and older who are scheduled for elective major surgery. Participants will be randomly assigned to either the SGB group (n=150) or the control group (n=150). In the SGB group, participants will receive an ultrasound-guided SGB using 7 mL of local anaesthetic, while the control group will receive 2 mL of saline injected into the muscle tissue on the anterolateral side of the SG. The primary outcome will be the occurrence of POD within 7 days postsurgery or before discharge. POD will be assessed two times per day using either the confusion assessment method (CAM) or the CAM for the intensive care unit. Secondary outcomes will include the severity of POD, postsurgical sleep quality, overall recovery quality and the incidence of adverse events.

Ethics and dissemination The trial protocol has been approved by the Ethics Committees of the Affiliated Hospital of Jiaxing University (approval number 2023-KY-479) and Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (approval number 2023–0747). Written informed consent will be obtained from all participants prior to study inclusion. Data collected will be disseminated at scientific conferences and published in peer-reviewed journals.

Trial registration number ChiCTR 2300077883.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A dual centre randomised controlled trial will be conducted in two tertiary hospitals.
⇒ Maintaining rigorous double-blinding will be a methodological challenge.
⇒ Some patients may be discharged before postoperative follow-up, potentially impacting the completeness of the data.
⇒ Patients may perceive their own grouping, leading to potential bias.
⇒ To minimise the effect of injection volume, we will implement different volume administration protocols.

INTRODUCTION

Postoperative delirium (POD) is a significant neurological complication, frequently observed in elderly patients following major surgeries. Previous studies have reported an incidence rate of approximately 30% for POD in patients undergoing major surgery.[1 2] POD is characterised by transient fluctuations in cognition, attention and consciousness, typically manifesting within the first week postsurgery or before hospital discharge.[3] POD is often associated with adverse postoperative outcomes, including an increased risk of bleeding, catheter-related complications, prolonged hospital stays and higher healthcare costs.[4–6] Furthermore, growing evidence suggests a significant association between POD and long-term cognitive decline.[7 8]

The occurrence of POD is a complex neurocognitive dysfunction influenced by multiple perioperative factors. Key contributors to POD include increased blood–brain barrier permeability, which leads to neuroinflammatory reactions,[9] reduced serum melatonin levels[10] and perioperative sleep disturbances.[11] SGB involves injecting local anaesthetic agents into tissues surrounding the SG, including the cervical sympathetic trunk, ganglia and associated nerves, thereby modulating sympathetic nervous system activity.[12] Recent research has demonstrated the efficacy of SGB in managing a range of conditions, such as

complex regional pain syndrome,[13 14] hot flashes,[15] sleep disturbances,[16] angina,[17] electric storm,[18] long Q-T syndrome[19] and postoperative pain.[20] Additionally, recent studies have highlighted further benefits of SGB, including reductions in postoperative inflammatory responses, increases in melatonin levels, stabilisation of perioperative haemodynamics and the mitigation of postoperative sleep disturbances.[21–24] SGB is considered a safe routine procedure. A survey conducted over 20 years ago involving 45 000 SGB cases revealed that, without the guidance of fluoroscopy or ultrasound, the incidence of severe adverse events was only 1.7 per 1000 procedures.[25] Recent high-quality studies have further confirmed that ultrasound-guided SGB is a safe and reliable procedure.[20 23]

Therefore, we hypothesise that SGB may enhance postoperative cognitive function in elderly patients through multiple mechanisms. However, there is a lack of clinical studies assessing the efficacy of SGB in preventing POD. This randomised controlled trial (RCT) protocol is designed to evaluate the effectiveness of ultrasound-guided SGB in preventing POD. Specifically, we aim to determine whether SGB reduces the incidence of POD in elderly patients undergoing major surgery compared with a control group. In addition, we will assess differences in POD severity,postoperative sleep quality, overall recovery quality and the incidence of complications between the SGB and control groups.

METHODS

This study is a dual-centre (Affiliated Hospital of Jiaxing University and Sir Run Run Shaw Hospital, Zhejiang University School of Medicine), participant-blinded and assessor-blinded RCT. The clinical trial protocol has been registered at the Chinese Clinical Trial Registration (ChiCTR2300077883). Elderly patients undergoing elective major surgery will be randomly divided into the SGB group (150 patients) and the control group (150 patients). The flow diagram of the study is illustrated in figure 1. This study was initiated on 12 April 2024 and is expected to conclude by 31 October 2025.

Eligibility criteria

Inclusion criteria

1. Patients aged ≥65 years, regardless of gender.
2. Scheduled for major surgeries under general anaesthesia, such as radical resections of malignant tumours in the upper abdomen (eg, liver, pancreas, stomach), hip replacement surgery, oesophageal and cardiac or large vessel surgeries.
3. American Society of Anesthesiologists (ASA) physical status classification of I–III.
4. Expected surgery duration of more than 2 hours and anticipated hospital stay greater than 3 days.
5. Ability to cooperate with the research process, use various evaluation scales and effectively communicate with researchers.

Exclusion criteria

1. Individuals with a history of psychiatric disorders.
2. Visual or auditory dysfunction.
3. History of opioid abuse.
4. Coagulopathy.
5. Allergy to ropivacaine.
6. Planned secondary surgery within 5 days.
7. Infection or other conditions that contraindicate SGB on the right cervical skin.

Exit criteria

1. The subject voluntarily withdraws informed consent at any time.
2. In the event of emergencies, such as the patient's death during or within 24 hours after surgery due to various reasons.
3. If the subject refuses to complete all postoperative evaluations as outlined in the trial protocol.
4. Serious protocol violations that impact the efficacy and safety evaluation of the trial.
5. Any other reasons determined by the researchers that render further participation in the trial inappropriate.

Randomisation and allocation concealment

Patients who meet the inclusion criteria will be randomly assigned to the SGB group or control group in a 1:1 ratio after signing the informed consent form. A trained nurse will use the DAP software (DAP Co, Beijing, China) to generate a blocked random number sequence in permuted blocks of four participants. Another nurse will seal the identification numbers and their corresponding allocation groups (SGB group or control group) in an opaque envelope. On the patient's arrival in the operating room, this nurse will open the envelope to reveal the allocation results and then prepare the injected medications, which will be either ropivacaine or saline.

Intervention

On entering the operating room, each patient will undergo standard monitoring using ECG, non-invasive blood pressure measurements, and pulse oximetry. A nurse will prepare the assigned medication based on the randomisation results: either 7 mL of 0.5% ropivacaine or 2 mL of normal saline. Ropivacaine (Qilu Pharmaceutical Co, China, concentration: 0.75%) will be used for the SGB. For the procedure, it will be diluted to a final concentration of 0.5% by mixing the appropriate volume of normal saline with the 0.75% solution. The patient will be positioned supine with the head tilted to the left and a thin cushion placed under the right shoulder to better expose the neck. The skin will be disinfected and patients will be instructed to avoid speaking, swallowing or making other movements during the procedure, raising their hands if they experience discomfort. A trained anaesthesiologist will use the SonoSite S series ultrasound machine

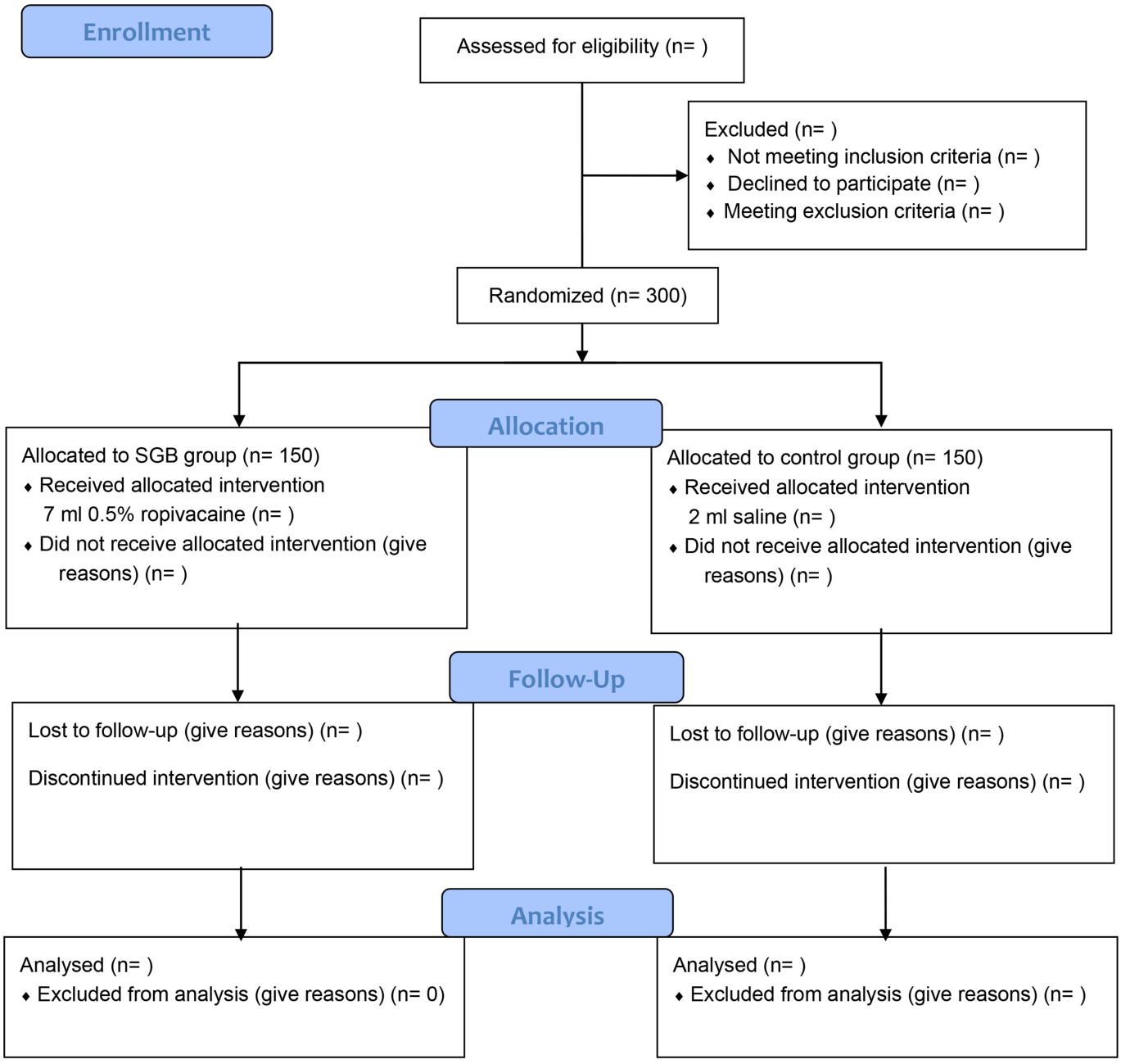

Figure 1 Study flow chart. SGB, stellate ganglion block.

(FUJIFILM SonoSite, Bothell, Washington, USA) to position the HFL38x/13–6 MHz high-frequency linear array probe horizontally at the C6 level. The internal jugular vein, common carotid artery and long neck muscle will be identified through transverse scanning. For patients in the SGB group, a 25-gauge needle will be inserted laterally at the level at C6, with the needle tip reaching the fascia plane of the sympathetic nerve chain, deep to the posterior fascia layer of the carotid sheath and superficial to the fascia covering the long neck muscle. After confirming negative pressure aspiration with no blood return, 7 mL of 0.5% ropivacaine will be injected into the SG. The anaesthesiologist will assess the success of the SGB based on the presence of Horner's syndrome, characterised by miosis, ptosis, enophthalmos, nasal congestion, conjunctival congestion, facial redness, absence of sweating and a warm sensation. Control group patients will receive 2 mL of saline injected into the muscle tissue on the anterior-lateral side of the right SGB under ultrasound guidance. All patients will be monitored for 20 min after the procedure. The anaesthesiologist performing the SGB will not participate in any other aspects of the study.

Another anaesthesiologist will administer general anaesthesia using the following induction drugs: propofol (1–2 mg/kg), sufentanil (0.5 µg/kg) and rocuronium (0.6–0.8 mg/kg). Mask-assisted ventilation will be conducted for 3–5 min, followed by visual laryngoscopy for tracheal intubation. Mechanical ventilation settings will include a tidal volume of 6–8 mL/kg, a frequency (f) of 12–16/min, an inspiratory-to-expiratory ratio of 1:1–2, an FiO_2

of 60–100% and a flow rate of 2 L/min. Intraoperative anaesthesia will be maintained with a combination of intravenous and inhalational agents: 1–2% sevoflurane, 2–4 µg/kg/hour propofol, 0.5–1 µg/kg/min remifentanil and intermittent boluses of 0.2–0.3 mg/kg rocuronium. Blood pressure and heart rate will be maintained within 20% of baseline values, with epinephrine (20–40 µg) and urapidil (5–15 mg) administered as needed for blood pressure regulation. Throughout the anaesthesia, respiratory parameters are adjusted to maintain $PetCO_2$ between 35 and 45 mm Hg, and the anaesthesia depth is regulated to keep the BIS value between 40 and 60. Postoperatively, patients will be transferred to the postanaesthesia care unit or intensive care unit (ICU) for further monitoring.

Blinding

Our study is a participant-blinded and assessor-blinded trial. Due to the inconsistent volumes of injected drugs and different block (sham or active), the nurse who dispenses the medication and the anaesthesiologist who performs SGB cannot be blinded. They do not participate in the subsequent study process and are informed that grouping information must not be disclosed. Surgeons, anaesthesiologists performing general anaesthesia, nurses conducting postoperative evaluations and statisticians are all blinded to the group allocation.

Outcome measurements

The primary outcome is the incidence of POD within 7 days after surgery or before discharge. A trained nurse will evaluate the patients two times per day (06:00-08:00 and 18:00-20:00). Patients are first evaluated using the Richmond Agitation-Sedation Scale (RASS). Further evaluation is performed for patients with RASS > −4. POD was evaluated by the confusion assessment method (CAM) or CAM-ICU. Both methods include the following four evaluation indicators: (1) changes in mental state or fluctuations in consciousness levels during acute attacks; (2) lack of concentration; (3) confused thinking and (4) changes in level of consciousness. If both features 1 and 2 are positive and at least one of the features 3 or 4 is positive, the diagnosis is delirium. Subtypes of delirium are classified according to RASS score: hyperactive type (RASS >0), hypoactive type (RASS<0), and mixed type (alternating between hypoactive and hyperactive types).

The secondary outcomes are as follows:

1. Delirium severity will be assessed using the Delirium Rating Scale-Revised-98. This scale features 16 items rated by clinicians and is divided into two sections: one with 13 severity items and another with three diagnostic items. Each severity item is scored from 0 to 3 points, while the diagnostic items are rated from 0 to 2 or 3 points.
2. Sleep quality will be evaluated using the Richards Campbell Sleep Questionnaire from the night before surgery up to 3 days postsurgery. This questionnaire consists of five items: sleep depth, sleep latency, frequency of waking, ease of returning to sleep and overall sleep quality. Responses are recorded on a 0–100 mm Visual Analogue Scale (1 mm=1 point). The total score, reflecting the average of the five items, indicates better sleep quality with higher scores.
3. Recovery quality will be measured using the 15-item Quality of Recovery Questionnaire (QoR-15) 3 days after surgery. The QoR-15 evaluates five dimensions of postoperative and anaesthesia recovery: comfort, emotional state, self-care capability, psychological support and pain.

Safety outcomes

Any complications related to the SGB procedure (eg, hoarseness, neck haematoma, toxic reactions to local anaesthesia, dizziness) or adverse events (eg, hypotension, bradycardia, cardiac arrest, arrhythmias, nausea, vomiting, opioid consumption) during the perioperative period will be documented. This documentation will include the diagnosis, occurrence time, resolution time, severity, relationship to the intervention, treatment and outcomes of adverse events. Serious adverse events will be reported to the Ethics Committee within 24 hours, whereas other events will be detailed in the final report. Patients experiencing adverse effects directly related to the study will receive compensation in accordance with legal standards.

Data and sample storage

All clinical trial paper data will be retained by the research secretary for at least 5 years after the termination of the study. Participants' demographic data, clinical laboratory results, disease history, surgical characteristics (including intraoperative analgesic use, regional anaesthesia application, blood loss/fluid infusion volume, surgical scope and duration, extubation time, postoperative sedation protocol, mobilisation time, etc), primary and secondary outcomes, and event data will be collected and stored in an electronic case report form via a secure electronic data capture (EDC) system. All users, including data entry personnel, investigators and monitors, will receive training to ensure accurate and consistent data entry. The EDC system employs security measures such as encryption, secure login and audit trails to protect data integrity and confidentiality. Access to the system will be restricted to authorised users. Data management computers are password-protected, and physical documents are securely stored. Participant identity information will remain confidential and will not be disclosed beyond what is permitted by applicable laws and regulations. There are no biological samples in this study.

Quality control of the trial

Prior to the start of the study, all anaesthesiologists, assessors and statisticians involved in the study were provided with standardised training on SGB procedures, inclusion and exclusion criteria, consistent observation times, evaluation of outcome measures and technical data processing.

Clinical supervisors will conduct periodic inspections of the study to ensure its quality.

Sample size

According to previous studies, the incidence of POD in elderly patients undergoing elective major surgery is approximately 25%.[1 2] We assume that the incidence of POD will decrease to 12% following SGB intervention. Using G*Power software (V.3.1.9.7), we set α to 0.05 and test power (1–β) to 0.8. Considering that approximately 10% of the sample size may be lost to follow-up in clinical studies, a total of 300 patients were included, with 150 patients in each group.

Statistical analysis

Participants in this study are required to undergo POD assessment 7 days after surgery (or until discharge). Considering that some patients may not comply with the protocol and may not be able to complete the entire follow-up process, we will first conduct a per-protocol analysis on those who have completed the entire evaluation process. Then, we will conduct intention-to-treat (ITT) analysis for patients in both groups who have not completed all evaluation procedures. All patients who undergo randomisation will be included in the ITT analysis.

All statistical analyses will be conducted using IBM SPSS Statistics V.22.0. Continuous data following a normal distribution will be presented as mean±SD, while data not following a normal distribution will be presented as median (IQR). Categorical data will be summarised as numbers (n) and percentages (%). For the primary outcome, the incidence of POD between the two groups will be compared using either the χ^2 test or Fisher's exact test. To adjust for potential imbalances in baseline or intraoperative variables, we will conduct a multivariable linear regression analysis. Variables with a standardised difference >0.10 in univariate analysis will be included as covariates in the adjusted model. To account for repeated measurements, we will employ a linear mixed-effects model, including random intercepts for each participant. The model will include fixed effects for time (continuous, scaled by day), treatment group and their interaction. Covariates including age, comorbidities, intraoperative data, analgesic consumption and complications will be included to control for potential confounders. Multivariable linear models will also be used to adjust for potential effect modifiers and explore interactions between treatment and covariates. For participants who are unable to provide data on sleep quality and quality of recovery, the data are considered missing. Missing data will be addressed using multiple imputation to account for missing values in the primary and secondary outcomes. Also, sensitivity analyses will be performed to evaluate the robustness of our estimates across different imputation models. Subgroup analysis will be performed based on preoperative cognitive function, gender, ASA physical status, anaesthesia duration and type of surgery.

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

Ethics and dissemination

This clinical trial was approved by the Affiliated Hospital of Jiaxing University (approval number 2023-KY-479) and Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (approval number 2023–0747). This clinical trial protocol has been registered at the Chinese Clinical Trial Registration (ChiCTR2300077883). Eligible patients will be enrolled after providing written informed consent to the investigator. The results of this study will be disseminated through peer-reviewed publications and/or presentations at conferences.

DISCUSSION

We will conduct a dual-centre, participant-blinded and assessor-blinded RCT to evaluate the efficacy of SGB in preventing POD in elderly patients undergoing major surgery and to further investigate its impact on postoperative recovery and sleep quality.

POD is a prevalent neurological complication in elderly patients following surgery, resulting in extended hospital stays, elevated costs, and a substantial burden on patients and their families.[26 27] A prospective cohort study conducted in the USA estimated that the 1 year postoperative costs associated with POD nationwide amount to approximately $32.9 billion.[28] In recent years, there has been growing interest in various intervention measures, both pharmacological and non-pharmacological, aimed at reducing the incidence of POD and alleviating its symptoms.[29–33] Our previous study found that dexmedetomidine can reduce the incidence of POD in patients undergoing non-cardiac surgery, though it is associated with risks of hypotension and bradycardia.[34] Animal experiments have indicated that preoperative SGB treatment can inhibit microglial activation, suppress TLR4/NF-κB-mediated neuroinflammation, and effectively mitigate postoperative cognitive decline.[22] However, there remains a scarcity of high-quality clinical studies on this topic. Consequently, we have designed and will implement a study to explore the effectiveness of SGB in preventing POD in elderly patients undergoing major surgeries. Meanwhile, studies have reported that SGB can improve postoperative pain and sleep quality in surgical patients.[35 36] Therefore, we will evaluate postoperative recovery and sleep quality as secondary outcomes in this study to further explore the effectiveness of SGB in enhancing recovery after surgery (ERAS).

This trial protocol has several potential limitations. First, the assessment of Horner's syndrome before anaesthesia may lead some patients to guess their group assignment, introducing potential bias. Second, some patients may be discharged before the 7-day postoperative follow-up, potentially impacting the completeness of the data.

Contributors GC substantially contributed to the study's conception, design and protocol refinement. Q-hS and JZ critically revised the study protocol and manuscript. X-bW and ZL handled data statistics and analysis. All authors reviewed and approved the final version and agreed to be accountable for all aspects of the work. Q-hS is the guarantor.

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Competing interests None declared.

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