Trials

STUDY PROTOCOL

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Comparison of postoperative analgesia effects between subcostal anterior quadratus lumborum block and transversus abdominis plane block in bariatric surgery: a prospective randomized controlled study

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Abstract

Background Currently, the prevalence of obesity is on the rise annually. Bariatric surgery stands out as the most efficacious approach for addressing obesity. Obese patients are more prone to experience moderate to severe pain after surgery due to lower pain thresholds. Regional block, as an important component of multimodal analgesia in bariatric surgery, is crucial in reducing opioid consumption and alleviating postoperative pain in patients undergoing bariatric surgery.

Transversus abdominis plane block (TAPB) has gained widespread utilization in bariatric surgery; however, its limitation of inadequate reduction of visceral pain in obese patients remains a significant concern. Therefore, it is imperative to explore new and more efficient strategies for analgesia. Quadratus lumborum block (QLB) has emerged as a popular nerve block in recent years, frequently utilized in conjunction with general anesthesia for abdominal surgery. In the cadaver study of QLB, it was confirmed that the dye level could reach up to T6 when using the subcostal anterior quadratus lumborum muscle approach, which could effectively reduce the incision pain and visceral pain of bariatric surgery patients during the perioperative period.

However, there is currently a lack of research on the use of subcostal anterior QLB in patients undergoing bariatric surgery. Our study aims to investigate whether subcostal anterior QLB can provide superior perioperative analgesic efficacy for bariatric surgery under general anesthesia compared to TAPB, leading to reduced postoperative opioid consumption and a lower incidence of postoperative nausea and vomiting (PONV).

Methods and design This study is a prospective, randomized controlled trial aiming to recruit 66 patients undergoing bariatric surgery. The participants will be randomly allocated into two groups in a 1:1 ratio: subcostal anterior QLB group ($n=33$) and TAPB group ($n=33$). The study aims to investigate the efficacy of subcostal anterior QLB and TAPB in obese patients who are scheduled to undergo bariatric surgery. Our primary outcome is to observe the amount of opioids used in the two groups 24 h after operation. The secondary outcomes included VAS of pain during rest/

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activity after operation, the type and dose of additional analgesics, the occurrence and severity of PONV, the type and dose of additional antiemetic drugs, postoperative anesthesia care unit (PACU) time, time of first postoperative exhaust, time to first out of bed activity, time to first liquid diet and postoperative admission days.

Discussion Opioid analgesics are prone to causing adverse reactions such as nausea, vomiting, and respiratory depression, especially in obese patients. Multimodal analgesia, including nerve block, can effectively reduce the dose of opioids and alleviate their adverse effects. Currently, TAPB is the most prevalent nerve block analgesia method for abdominal surgery. Recent studies have indicated that subcostal anterior QLB offers advantages over TAPB, including a wider block plane, faster onset, and longer maintenance time. It is not clear which of the two nerve block analgesia techniques is better for postoperative analgesia in patients undergoing bariatric surgery. Our objective in this investigation is to elucidate the superior method between TAPB and subcostal anterior QLB for postoperative pain management in bariatric surgery.

Trial registration ChiCTR ChiCTR2300070556. Registered on 17 April 2023.

Keywords Subcostal anterior quadratus lumborum block, Transversus abdominis plane block, Bariatric surgery, Obesity, Analgesia, Randomized controlled clinical study

Introduction

Background and rationale {6a}

At present, the incidence rate of obesity is on the rise. More than 2.2 billion adults in the world are overweight, of which about 600 million are obese [1]. The most effective approach to addressing obesity is bariatric surgery, which has been shown to significantly enhance the quality of life for patients and reduce the incidence of complications related to obesity [2]. Relevant research indicates that obese individuals exhibit a lower pain threshold and are more susceptible to experiencing pain [3]. Despite the increasing use of laparoscopic surgery, obese patients continue to experience moderate to severe postoperative pain following bariatric surgery, which significantly impacts their recovery speed and satisfaction [4]. Opioid drugs currently serve as the primary intravenous analgesics for bariatric surgery; however, their adverse effects are particularly pronounced in obese patients, including postoperative nausea and vomiting (PONV) and respiratory depression. Over the past 2 years, anesthesiologists have shown increasing interest in exploring the role of less opioid anesthesia strategies in promoting rapid recovery and alleviating pain following abdominal surgery [5].

As an important part of multimodal analgesia, regional block is crucial in reducing opioid consumption and alleviating pain. The common methods of regional block are epidural analgesia and nerve block.

Although relevant studies have confirmed the efficacy of epidural analgesia in reducing pain for patients undergoing bariatric surgery [6, 7], its application is limited by a high rate of puncture failure.

Since its initial proposal, transversus abdominis plane block (TAPB) has been utilized in abdominal surgeries [8] and has emerged as one of the most prevalent methods for analgesia in such procedures. In 2019 [9], a retrospective analysis of 191 patients undergoing bariatric surgery found that patients receiving TAPB before surgery could significantly reduce the use of intravenous and oral opioid consumption during the perioperative period. Meta-analysis of 10 randomized controlled trials (RCTs) [10] confirmed that among 404 patients receiving TAPB, their early and late VAS were significantly improved during rest and exercise, the consumption of opioids was reduced 24 h after operation, and the incidence of PONV was reduced, and no adverse reactions were reported in any study. However, because TAPB can only block the abdominal wall nerve, the relevant research has not reflected its advantages for postoperative pain after abdominal surgery.

The quadrus lumborum block (QLB), a popular regional nerve block option in recent years, is frequently combined with general anesthesia for abdominal surgery. Previous studies have demonstrated that QLB use in abdominal surgery can lead to reduced opioid consumption and provide analgesia lasting up to 24 h [11, 12].

The application of anterior QLB in bariatric surgery is supported by its relevant anatomical and theoretical basis. Elsharkway H et al. [13] demonstrated that the drug diffused to T7–L2, up to the T6 level, when using the subcostal anterior approach at the L1–L2 level of a cadaver. Additionally, in a cadaver study, it was observed that the dye diffused into the thoracic paravertebral space, the intercostal space around the somatic nerve, and even the thoracic sympathetic trunk [14, 15]. Therefore, this plane range can effectively assist in managing pain stress for patients during perioperative analgesia of bariatric surgery, including visceral pain and abdominal wall incision pain. Currently, clinical research has demonstrated that [16], the anterior QLB exhibits rapid onset, prolonged duration, and a broad block plane.

However, there is currently a paucity of relevant research on the utilization of subcostal anterior QLB in patients undergoing bariatric surgery. Considering the advantages of reaching the thoracic paravertebral space, the nerves that may transmit visceral pain, and the possibility of covering the T6–L2 segment, we assume that compared with TAPB, subcostal anterior QLB can provide better postoperative analgesia for bariatric surgery.

Objectives {7}

The aim of this trial is to compare the efficacy of subcostal anterior QLB with TAPB in managing postoperative pain following bariatric surgery.

Trial design {8}

This is a single-center, randomized controlled trial to be conducted at the Peking University Shenzhen Hospital. The study flowchart is depicted in Fig. 1. Patients scheduled for bariatric surgery will be enrolled and randomly allocated to either the TAPB group or the subcostal anterior QLB group in a 1:1 ratio. This work was supported by the General Program for Clinical Research at Peking University Shenzhen Hospital (No.LCYJ2022028).

If the principal investigator(PI) proposes any amendments to the protocol, the revised protocol will be resubmitted to the Ethics Committee and submitted to the clinical trial registries at the same time.

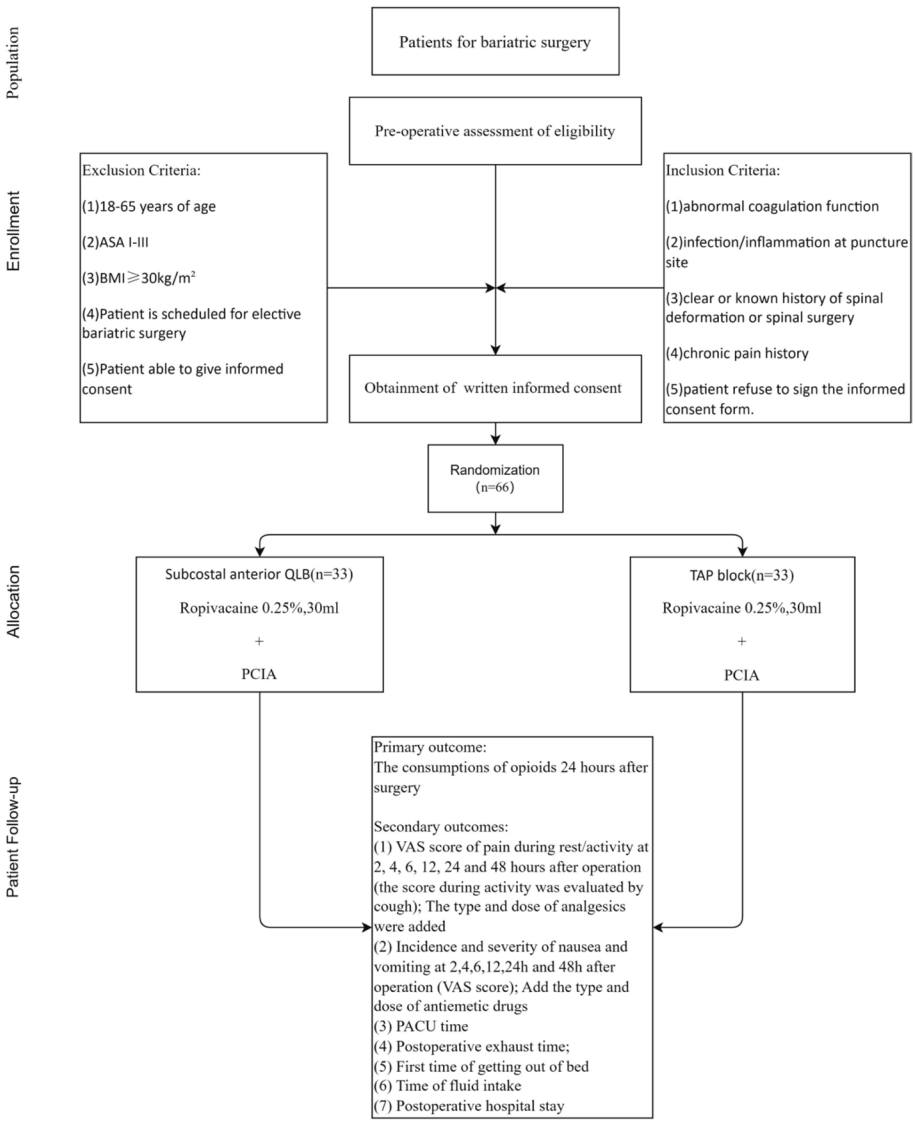

Fig. 1 Flow diagram of the study. ASA, American Society of Anesthesiologists classification of physical status; BMI, body mass index; QLB, quadratus lumborum block; TAP block,transversus abdominis plane block; PCIA, patient-controlled intravenous analgesia; VAS, visual analog scale; PACU, postanesthesia care unit

Methods: participants, interventions, and outcomes

Study setting {9}

Participants will be recruited from the Gastrointestinal Surgery Department (secondary care center) at Peking University Shenzhen Hospital in Shenzhen, China. All research procedures will be conducted in the operating room and wards of Peking University Shenzhen Hospital. The research procedures, including nerve block, general anesthesia, and surgical treatment, will be performed in the operating room. Standardized postoperative care and postoperative follow-up records will be provided in the wards.

Eligibility criteria {10}

Inclusion criteria: (1) 18–65 years of age, (2) American Society of Anesthesiologists (ASA) physical status I to III, (3) body mass index (BMI) ≥ 30 kg/m^2, (4) patients are scheduled for elective bariatric surgery, and (5) patients voluntarily participate in the trial and sign an informed consent form.

Exclusion criteria: (1) abnormal coagulation function, (2) infection/inflammation at the puncture site, (3) clear or known history of spinal deformation or spinal surgery, (4) chronic pain history, and (5) patient refuses to sign the informed consent form.

Who will take informed consent? {26a}

Eligible participants will be supervised by designated members of the research team to participate in the study. The researchers will provide the patient with a comprehensive explanation of potential risks. If the patient consents to participate in the study, the researchers will present a detailed description of the trial at their bedside and request the patient to sign a written informed consent form. The signed informed consent form will be securely stored in the clinical research archives of the Department of Anesthesiology at Peking University Shenzhen Hospital.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable. We will not collect and use participant data and biological specimens in auxiliary studies.

Interventions

Explanation for the choice of comparators {6b}

Since its initial proposal, TPAB has been extensively utilized in abdominal surgery, and TAPB has also demonstrated analgesic effects in bariatric surgery [9]. In this study, TAPB is chosen as the control group, rather than a blank control group, based on its analgesic effect advantage, which can maximize the benefits for patients. Furthermore, choosing TAPB as the comparator is more appropriate because the study aims to explore management strategies that are more effective in relieving the pain associated with bariatric surgery, thus requiring a comparison with proven effective pain management strategies. However, due to its limited mechanism of action, TAPB can only alleviate incisional pain rather than visceral pain, which is precisely the advantage of subcostal anterior QLB. There is currently a dearth of prospective clinical studies comparing the analgesic efficacy of TAPB and anterior subcostal QLB in obese patients.

Intervention description {11a}

QLB group

In the surgical setting, researchers will adhere to standardized protocols for monitoring participants' vital signs. Participants will be instructed to assume a supine position. Subsequently, the researchers will meticulously sterilize and drape the surgical site before positioning the low-frequency probe at an angle of 6–8 cm outside the L1–2 spinous processes, on the lateral aspect where the erector spinae muscle and iliocostalis muscle intersect. It will be observed that the quadratus lumborum muscle is below the 12th rib margin, where there are only latissimus dorsi muscle and serratus posterior inferior muscle behind the quadratus lumborum muscle, and there is the anterior layer of the thoracolumbar fascia, diaphragm, perirenal fat, and kidney in front of the quadratus lumborum muscle. Move the probe to the inside, and the latissimus dorsi muscle gradually thins until it disappears. At this time, the erector spinae muscle is located behind the quadratus lumborum muscle, and the psoas major muscle is located in front of it. The researchers will inject 3 ml of normal saline between the quadratus lumborum and the anterior layer of thoracolumbar fascia through the pump tube and puncture needle to confirm that the liquid diffuses in the target space. Then the drug solution of 0.25% ropivacaine will be given 30 ml. Afterwards, the researchers will replicate the procedure on the opposite side of the subject and then instruct them to assume a supine position. The researchers will use a bottle with ice to test the coverage of the skin layer with a sensory block. General anesthesia will be performed after the test (Fig. 2).

If the researchers have difficulty or failure with the puncture, the trial will be terminated in accordance with standard procedures, and the participant will receive general anesthesia. Subsequently, they will undergo follow-up until discharge to assess any potential adverse events resulting from a failed nerve block.

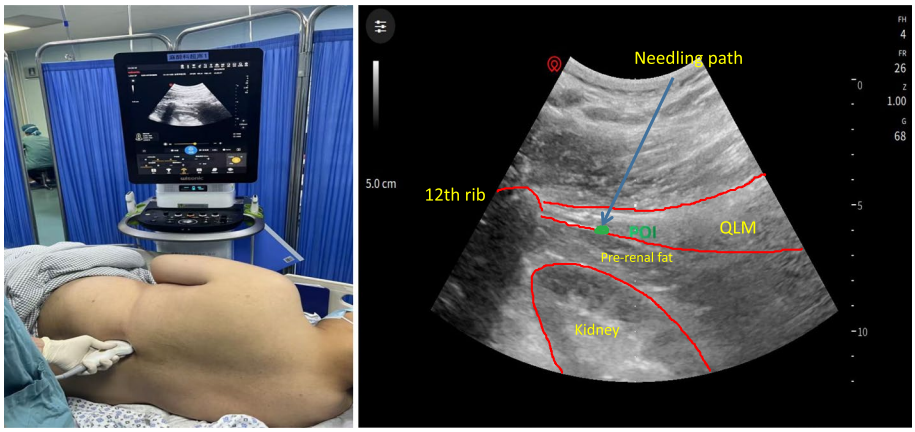

Fig. 2 The position of the patient preparing for subcostal anterior QLB and the placement of the ultrasound probe. Ultrasound images of anatomy, needle targets, and injection points. QLM, quadratus lumborum muscle; kidney and pre-renal fat; 12th rib; POI, point of injection with needling path

TAPB group

In the surgical setting, researchers will adhere to standardized protocols for monitoring participants' vital signs. Participants will be instructed to assume a lateral recumbent position. The researchers will place the ultrasound probe vertically above the iliac crest and move the probe upwards once they see the iliac crest. From the outside to the inside, the researchers will see the fat layer, external oblique muscle, internal oblique muscle, and transverse muscle. The researchers will employ a puncture needle to penetrate from the front/inside direction, passing through the fat layer, external oblique muscle, and internal oblique muscle. The needle tip will be located at the superficial part of the transverse abdominal fascia. Three milliliters of normal saline will be given through the pump tube and puncture needle to confirm the liquid diffusion in the target space. Then the drug solution of 0.25% ropivacaine will be given 30 ml. Afterwards, the researchers will replicate the procedure on the opposite side of the subject. The researchers will use a bottle with ice to test the coverage of the skin layer with a sensory block. General anesthesia will be performed after the test (Fig. 3).

If the researchers have difficulty or failure with the puncture, the trial will be terminated in accordance with standard procedures, and the participant will receive general anesthesia. Subsequently, they will undergo follow-up until discharge to assess any potential adverse events resulting from a failed nerve block.

Criteria for discontinuing or modifying allocated interventions {11b}

The criteria for withdrawal from the trial are as follows: (1) If participants request to withdraw from the trial prior to successful implementation of the nerve block, researchers will provide standard treatment and cease

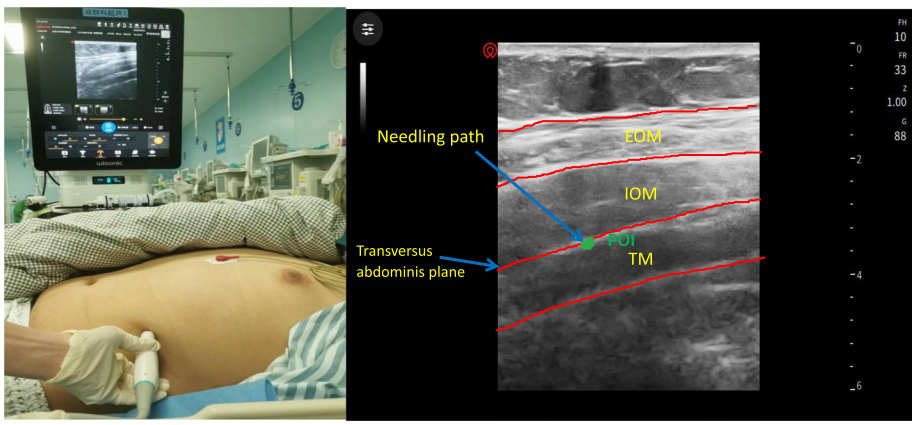

Fig. 3 The position of the patient preparing for TAPB and the placement of the ultrasound probe. Ultrasound images of anatomy, needle targets, and injection points. EOM, external oblique muscle; IOM, internal oblique muscle; TM, transverse muscle; TAP, transversus abdominis plane; POI, point of injection with needling path

data collection. Once the nerve block is successfully implemented, participants will no longer be able to withdraw from the trial. (2) Due to unforeseen circumstances (such as failure in performing nerve block), the researchers reserve the right to terminate the study.

Strategies to improve adherence to interventions {11c}

Comprehensive informed consent process: During the recruitment stage, it is essential to ensure that participants are provided with well-defined, comprehensive, and easily comprehensible informed consent documents. These documents should encompass detailed information on the study objectives, procedures, potential risks, and benefits. It is imperative to confirm that participants have a full understanding of the study and participate voluntarily. Meanwhile, the researchers will inform the patients that once the nerve block is successfully performed, they will not be able to decline participation in the trial.

Collaborative efforts by medical teams: Effective collaboration among members of the medical team should be ensured to address potential issues affecting adherence. A cohesive medical team can proficiently tackle challenges related to participant adherence.

Privacy and data protection measures: Participants must be assured of robust data protection measures and efforts made towards ensuring anonymity where feasible. This approach serves to allay concerns and bolster trust in the research process among participants.

Relevant concomitant care permitted or prohibited during the trial {11d}

Induction and maintenance of anesthesia

Irrespective of group allocation, the anesthesia induction protocol consisted of propofol 2 mg/kg, sufentanil 0.4 μg/kg, rocuronium 0.6 mg/kg, and dexamethasone 5 mg under general anesthesia. The doses of propofol and rocuronium will be calculated based on the patient's total body weight, while the dose of sufentanil will be determined by the lean body weight (LBW): male LBW (kg) = 9270 × ideal body weight (kg)/(6680 + (216 × BMI (kg/m^2)), female LBW (kg) = 9270 × ideal body weight (kg)/(8480 + (244 × BMI (kg/m^2)). After 3 min, intubate the trachea and perform mechanical ventilation. Adjust the parameters of the ventilator. The tidal volume (VT) is 6–8 ml/kg. The tidal volume is calculated according to the ideal weight. The ideal weight (kg) = height (cm) − 105 (female 100). The respiratory rate is adjusted based on the end-tidal carbon dioxide level and maintained within the range of 35–45 mmHg. The pneumoperitoneum pressure is set to 12 mmHg. Administer sevoflurane and remifentanil for maintenance of general anesthesia, while ensuring the bispectral index remains within the range of 40 to 60. Blood pressure is regulated to stay within 20% of baseline levels. Muscle relaxation is achieved through intermittent intravenous injection of rocuronium. Ten milligrams of azasetron and 50 mg of flurbiprofen are administered via intravenous injection 20 min before the end of the surgery. After the surgical procedure, both groups received patient-controlled intravenous analgesia (PCIA). The PCIA regimen consisted of sufentanil 100ug diluted in 100 ml of normal saline to achieve a concentration of 1 μg/ml. There was no background dose and a single bolus dose of 5 ml with a lock-in time of 15 min and a limiting dose of 20 ml/h. The PCIA medication would be replenished as needed for up to 48 h post-operation.

The patient was transferred to the post-anesthesia care unit (PACU) following the surgical procedure, where continuous monitoring of vital signs will be conducted throughout the recovery period. In PACU, the severity of pain at rest and during activity will be assessed by the visual analog scale (VAS) (0 = no pain, 10 = the most severe pain imaginable). If PCIA is fully utilized but significant surgery-related pain persists, additional injections of sufentanil at a dose of 5 μg each time may be administered until the VAS score is ≤ 3.

PONV during PACU will be treated by intravenous injection of 1 mg of droperidol. The patient will only be transferred to a ward once they no longer experience postoperative nausea or vomiting.

The postoperative treatment protocol for patients in the ward is as follows: during the initial 48-h period following surgery, patients will be administered PCIA therapy in conjunction with a 50-mg intravenous infusion of flurbiprofen every 12 h. If the patient's VAS remains ≥ 4 within this timeframe, an intravenous injection of 100 mg tramadol may be given, with a maximum daily dosage not to exceed 400 mg.

Provisions for post-trial care {30}

In the event of a participant experiencing a complication related to the intervention, a multidisciplinary team consisting of surgical, anesthesia, and nursing professionals will provide standard postoperative management. Additionally, our team will closely monitor participants throughout their hospitalization to ensure freedom from potential complications and to deliver timely treatment as necessary. Our aim is to ensure that all participants receive the highest quality of treatment and care during the trial.

Outcomes {12}

Primary outcome

As the primary outcome, we will evaluate the consumption of opioids 24 h after surgery.

Secondary outcomes

The secondary outcomes included the following: (1) VAS of pain during rest/activity at 2, 4, 6, 12, 24, and 48 h after operation (the score during activity will be evaluated by cough); add the type and dose of analgesics; (2) incidence and severity of nausea and vomiting at 2, 4, 6, 12, 24, and 48 h after operation(VAS); add the type and dose of antiemetic drugs; (3) PACU time; (4) time of first flatus postoperatively; (5) time of first ambulation postoperatively; (6) Time of first liquid diet postoperatively; and (7) postoperative admission days.

Participant timeline {13}

The schedule for enrollment, intervention, and evaluation is depicted in Figs. 1 and 4.

Sample size calculation {14}

In the preliminary trial, we administered TAPB for postoperative analgesia to 10 patients who underwent bariatric surgery. The average consumption of sufentanil during the first 24 h after surgery was 56.5 (SD = 15.4) μg. We used the software of PASS 2021 to calculate the sample size. We hypothesized that the use of subcostal anterior QLB for postoperative analgesia in patients undergoing bariatric surgery would result in a 20% reduction in sufentanil consumption compared to the TAPB group, with a significance level of $\alpha = 0.05$. With an inspection efficiency of $1-\beta = 0.80$ and a 1:1 grouping, we calculated that 30 patients are required for each group. Requiring a 10% allowance for lost cases, each group will need 33 patients, resulting in a total of 66 patients needed for the study.

Recruitment {15}

Participants will be recruited via social media platforms (e.g., WeChat), promotional materials, and online news outlets. Furthermore, a variety of recruitment strategies will be employed, including in-person invitations during clinic visits and referrals from various medical disciplines. Following participant selection, research personnel will assume responsibility for identifying and enrolling eligible individuals who meet the inclusion criteria.

Assignment of interventions: allocation

Sequence generation {16a}

In this study, participants will be randomly assigned to either TAPB or subcostal QLB in a 1:1 ratio generated by the computer using SPSS version 27 (SPSS, Inc., Chicago, IL, USA). The randomization process will be overseen by an independent individual to ensure unbiased assignments and mitigate potential confounding factors.

	Enrolment	Allocation	Post-allocation								Close-out
Time point	0	B0	B0	T0 Post-extubation	T0 Post-extubation +2h	T0 Post-extubation +4h	T0 Post-extubation +6h	T0 Post-extubation +12h	T0 Post-extubation +24h	T0 Post-extubation +48h	Day of discharge
ENROLMENT											
Eligibility screen	×										
Informed consent	×										
Allocation		×									
INTERVENTIONS											
QLB-group			×								
TAPB-group			×								
ASSESSMENTS											
Baseline dataset	×	×									
Opioid consumption					×	×	×	×	×	×	
VAS of pain during rest and activity					×	×	×	×	×	×	
Incidence and severity of nause and vomiting					×	×	×	×	×	×	
Type and dose of analgesics					×	×	×	×	×	×	
Type and dose of antiemetic drugs					×	×	×	×	×	×	
Adverse events					×	×	×	×	×	×	×

Fig. 4 SPIRIT figure. Standard Protocol Items: Recommedations for Interventional Trials (SPIRIT). h, hours; QLB, quadratus lumborum block; TAPB, transversus abdominis plane block; VAS, visual analog scale

By utilizing computer-generated randomization and oversight by an independent party, we aim to uphold the highest standards of scientific rigor and integrity in our study.

Concealment mechanism {16b}

In order to ensure the impartiality of randomization, the participants' codes and groups will be placed in an opaque envelope and sealed, which will be securely held by the PI. This approach serves to minimize potential selection bias and guarantees that participants are allocated to study groups in an unbiased manner. A research coordinator will also be designated, with responsibilities including storage and distribution of random numbers, preparation of drugs, and coordination of information among researchers. During the postoperative follow-up period, personnel conducting follow-up assessments will remain blinded to participant group assignments in order to mitigate bias in follow-up results and ensure equitable outcomes.

Implementation {16c}

Eligible patients receive informed consent the day before surgery, and the PI and researchers open sealed, opaque envelopes containing the corresponding patient code to ensure the integrity of the randomization process and minimize the influence of potential confounding factors.

Assignment of interventions: blinding

Who will be blinded {17a}

Due to the differing implementation processes of TAPB and subcostal anterior QLB interventions, it is not feasible to blind the researchers conducting the interventions. However, in order to minimize potential bias, the statisticians and post-operative follow-up personnel will be blinded to group allocation to ensure that the data analysis is unbiased and prevent potential confounding factors.

Procedure for unblinding if needed {17b}

If the trial participants meet the criteria for study termination, the group assignments will be disclosed to the public.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Data for this study will be recorded in a Case Report Form (CRF) or collected from an electronic medical record system. An independent investigator will conduct the data collection process to mitigate potential bias. Before collecting any information, all investigators are required to undergo training provided by the primary investigator on proper methods of collecting, recording, and storing data. In order to maintain the confidentiality of the collected information, it is imperative that all details are kept strictly confidential throughout this process. After the completion of data collection, the researchers will transcribe the data into Microsoft Excel for analysis. Subsequently, PI will conduct a comprehensive review of the original datasets to identify any critical missing or erroneous entries.

The PI shall remain unaware of groupings until after the completion of our analysis so as not to introduce any potential biases that may compromise the validity within our findings.

Plans to promote participant retention and complete follow-up {18b}

In this clinical trial, all participants will receive post-operative follow-up until discharge to ensure the timely detection and documentation of potential complications. Prior to obtaining informed consent, participants will be provided with comprehensive information about the study protocol and procedures to promote full comprehension and cooperation. Our research team is committed to addressing any unforeseen issues that may arise during follow-up, including patient discomfort or complications, in order to facilitate a thorough and accurate post-operative assessment. Furthermore, we will proactively engage with participants after surgery to enhance patient compliance and minimize the risk of missed follow-up.

Data management {19}

The data of all participants will be recorded in CRFs, then cross-validated and transcribed into Microsoft Excel by two researchers simultaneously. These electronic research records will be securely stored on a password-protected computer under the supervision of the PI, who will have exclusive access to the research data.

Confdentiality {27}

During the trial period, all patient information and research data will be encrypted and securely stored in a designated cabinet with restricted access. The PI will have exclusive access to the safety lock, ensuring the confidentiality of patient information and research data.

Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable, as this study does not collect samples from patients.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

All statistical tests are two-sided. A *P* value less than or equal to 0.05 will be considered statistically significant (unless otherwise specified). The Shapiro–Wilk test is used to assess the normal distribution of the data. Quantitative indicators will be presented as mean and standard deviation (M ± SD) or median and range (minimum to maximum), along with demographic information such as age, height, weight, BMI, etc., analgesic and antiemetic drug dosage, pain VAS, nausea and vomiting VAS, as well as various time intervals (PACU time, time of first flatus postoperatively, time of first ambulation postoperatively, time of first liquid diet postoperatively, postoperative admission days). Categorical variables will be described in terms of frequency and percentage for each category along with demographic information including gender, preoperative comorbidities, ASA physical status classification system scores, etc., types of analgesics and antiemetics administered, adverse events related to nerve blocks, etc., all being subjected to appropriate statistical analysis based on their respective numerical characteristics.

Interim analyses {21b}

The interim analysis was not included in the plan.

Methods for additional analyses (e.g., subgroup analyses) {20b}

Additional analyses are not planned for this study.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

According to the design of our study, we have minimized the risk of data loss. If missing data cannot be ignored, our research team will utilize single interpolation techniques to accurately estimate missing values.

Plans to give access to the full protocol, participant-level data, and statistical code {31c}

The data analysis will be conducted rigorously and transparently to ensure the accuracy and reliability of our conclusions. Upon reasonable request, the PI will provide interested researchers with the statistical codes used for analysis. Furthermore, in accordance with the data retention policy, all completed data will be retained for a period of 5 years after the completion of the study. All data will be securely stored and maintained in compliance with relevant data protection laws and regulations.

Oversight and monitoring composition of the coordinating center and trial steering committee {5d}

The trial is a single-center clinical study, and all participants will receive care and treatment at the same research site. To ensure effective and smooth implementation of the trial, a steering committee consisting of two experienced clinical researchers will be established. The committee will be responsible for monthly monitoring of trial progress, data review, and resolution of any issues that may arise during the trial. It will play a critical role in ensuring study integrity and quality, providing guidance and support to the research team, and ensuring compliance with ethical and regulatory standards. Additionally, the committee will oversee participant safety and health, as well as adjust the trial protocol if necessary to optimize treatment outcomes for all participants.

Composition of the data monitoring committee, its role, and reporting structure {21a}

Due to the limited sample size, a data monitoring committee was not established. The collection of data is expected to be completed within a 12-month period.

Adverse event reporting and harms {22}

TAPB and subcostal anterior QLB have been safely implemented in clinical practice following thorough technical validation. Any adverse events posing a risk to patients or unexpected side effects will be systematically documented and reported, leading to immediate suspension or termination of the study.

Frequency and plans for auditing trial conduct {23}

The implementation of an audit procedure is to ensure the accuracy and completeness of the data in this trial, with quarterly audits planned. The procedure will encompass a comprehensive review of all study data, including verification of missing data, confirmation of the accuracy and quality of raw data, and consultation on the overall progress of the study.

Plans for communicating important protocol amendments to relevant parties (e.g., trial participants, ethical committees) {25}

The study protocol has been approved by the Ethics Committee of Peking University Shenzhen Hospital and registered with the Chinese Clinical Trial Registry. Any modifications to the protocol must receive approval from the principal investigator and be resubmitted to the Ethics Committee of Peking University Shenzhen for review and endorsement.

Dissemination plans {31a}

After the trial, the results will be disseminated through peer-reviewed academic journals and presented at international academic conferences. Our study aims to advance current knowledge of perioperative analgesia management in patients undergoing bariatric surgery and to provide clinicians with enhanced analgesia options.

Discussion

Regional block plays an important role in multimodal pain management. Previous studies have shown that abdominal wall blocks such as TAPB are effective in managing postoperative pain for patients undergoing abdominal surgery [17–19]. However, some research findings have indicated that the analgesic efficacy of TAPB is suboptimal [20, 21], which may be attributed to the fact that most abdominal wall blocks primarily alleviate pain in the abdominal wall and incision, but have limited impact on visceral pain. In order to address visceral pain, it is necessary for the local anesthetic to be diffused into the paravertebral space. During anterior QLB procedures, the anticipated spread of local anesthetics can effectively block visceral nerves by reaching the paravertebral region. When performing nerve blocks beneath the ribs, the blocking plane has the potential to reach T6–L2.

The anterior QLB was performed in the fascial plane between the quadratus lumborum and psoas major. In comparison to more superficial blocks (such as TAPB block and lateral QLB), the advantage of anterior QLB lies in its deeper location, potentially allowing for greater paravertebral diffusion [22]. Due to the potential paravertebral diffusion observed in some studies, the anterior QLB may offer more dependable visceral analgesia [23]. However, given that the injection site of anterior QLB is deeper in anatomy and closer to the abdominal viscera, the technical demands for performing anterior QLB are higher compared to TAPB [24]. The reported complications of TAPB and anterior QLB include visceral injury, local anesthetic toxicity, bleeding risk of anticoagulant patients, and muscle weakness of quadriceps femoris [24–26].

To date, the optimal analgesia strategy for patients undergoing bariatric surgery remains uncertain. Given the significance of pain management, our study aims to investigate whether subcostal anterior QLB can offer superior pain control and reduce opioid consumption compared to the commonly utilized TAPB in bariatric surgery.

Trial status

The trial will be conducted in accordance with the principles of the Declaration of Helsinki and all regulatory requirements. Approval for this study was obtained from the ethics committee of Peking University Shenzhen Hospital on March 22, 2023. The study has been registered at the China Clinical Trial Registration Center under registration number ChiCTR2300070556. The trial recruitment commenced in September 2023. We are presently engaged in this investigation and anticipate its conclusion by April 2025.

Abbreviations

TAPB	Transversus abdominis plane block
QLB	Quadratus lumborum block
PONV	Postoperative nausea and vomiting
ASA	American Society of Anesthesiologists
PACU	Postoperative anesthesia care unit
PCIA	Patient-controlled intravenous anesthesia
BMI	Body mass index
LAST	Local anesthetic systemic toxicity
VAS	Visual analog scale
PI	Principal investigator
RCT	Randomized controlled trial

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08359-4.

Supplementary Material 1.

Acknowledgements

Assistance with the study: we thank our research coordinator Shuang Yin for her invaluable assistance.

Roles and responsibilities: contributorship{5a}

Authors' contributions

LBC and WXH designed the study. LBC performed the sample size calculation. LWH, YY, and RLW are responsible for the postoperative follow-up and data collection. YS provides statistical analysis. All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication, no professional writers have been involved. All authors read and approved the final manuscript.

Funding {4}

This work was supported by the General Program for Clinical Research at Peking University Shenzhen Hospital (No.LCYJ2022028).

Availability of data and materials {29}

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate {24}

Informed consent will be obtained from all participants in the study, which was approved by the Ethics Committee of Peking University Shenzhen Hospital on March 22, 2023. Furthermore, this study has been registered at the China Clinical Trial Registration Center with the following number: ChiCTR2300070556.

Consent for publication {32}
All the participants will be assigned an informed consent form. This form includes the publication consent.

Competing interests {28}
The authors do not have any competing interests, financial or otherwise, to report.

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Received: 24 September 2023 Accepted: 30 July 2024
Published online: 03 August 2024

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