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STUDY PROTOCOL

Effect of Low Thoracic Paravertebral Block via the Arcuate Ligament Under Direct Visualization on the Quality of Postoperative Recovery After Laparoscopic Donor Nephrectomy for Living-Donor Kidney Transplantation: Study Protocol for a Prospective, Blinded, Randomized Controlled Clinical Trial

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Introduction: Laparoscopic donor nephrectomy (LDN) is the standard procedure for donor nephrectomy for living kidney transplantation. Compared with traditional open surgery, the laparoscopic techniques have been developed to significantly reduce postoperative pain and accelerate postoperative recovery; however, most donors still experience more than moderate pain after surgery. Ensuring maximum perioperative safety and postoperative pain control for donors remains a top priority for LDN. Our group reported a novel blockade technique that allows local anesthetic to be injected directly to reach the low thoracic paravertebral space under direct laparoscopic observation via the arcuate ligament to achieve somatic and visceral pain analgesia; this technique has been successfully applied to patients undergoing retroperitoneal laparoscopic nephrectomy. We hypothesized that compared with the transversus abdominis plane (TAP) block, low thoracic paravertebral block (TPVB) via the arcuate ligament under direct vision would reduce the consumption of postoperative opioids and improve the quality of postoperative recovery of donors after LDN.

Methods/Analysis: This study is a prospective blind, randomized, controlled clinical trial with a concealed allocation of donors scheduled to undergo elective LDN 1:1 to receive either a low TPVB via the arcuate ligament under direct vision or a TAP block. This study will recruit a total of 82 living kidney donors. The primary outcome is the 15-item recovery quality scale (QoR-15) score at 24 hours after surgery.

Ethics and Dissemination: This trial was approved by the Ethics Committee of Beijing Friendship Hospital, Capital Medical University. This trial study protocol was approved on 30 November 2024. The trial started recruiting patients after being registered on the Chinese Clinical Trial Registry.

Trial Registration Number: ChiCTR2400094612.

Keywords: thoracic paravertebral block, arcuate ligament, laparoscopy, living donor nephrectomy

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Introduction

Kidney transplantation is the most effective treatment for end-stage renal disease. The demand for living-donor kidney transplantation (LDKT) has increased worldwide due to the shortage of organs from deceased donors, and LDKT has advantages demonstrated over deceased donor kidney transplantation in terms of graft survival and reduction of warm ischemia time.[1–3] Since its initial description in 1995, laparoscopic donor nephrectomy (LDN) has become the standard procedure for kidney procurement for living kidney transplantation, replacing the traditional open surgery.[4] Compared to open surgery, laparoscopic techniques offer more advantages such as reduced postoperative pain, shorter hospital stays, and quicker recovery.[5,6] However, it is noteworthy that the majority of donors still experience more than moderate pain in the postoperative period.[7] The level of postoperative pain is also a common question asked by donors before surgery, which may affect the quality of the donor's postoperative recovery and the anticipated level of life and work, especially important when voluntary and rescuing their loved one. It has been shown that there is a significant correlation between recovery time after kidney donation and acute postoperative pain or discomfort.[8] Since living kidney donors are healthy people, ensuring maximum perioperative safety and postoperative pain control is a top priority for LDN. Therefore, it is crucial to adopt an effective analgesic regimen to minimize postoperative pain and promote postoperative recovery in donors with LDN.

Patient-controlled intravenous analgesia (PCIA) with opioid analgesics is the most commonly used method for the treatment of postoperative pain in donors with LDN. However, the postoperative pain side effects of opioids such as nausea, vomiting, and itching, can interfere with patient recovery. Thoracic epidural analgesia (TEA) has been regarded as the gold standard for pain control after laparoscopic nephrectomy.[9] However, the risk-benefit ratio of TEA needs to be evaluated critically, as the donors are healthy individuals, especially young donors. In some studies, ultrasound-guided transversus abdominis plane (TAP) block is also indicated for laparoscopic nephrectomy, as it reduces postoperative pain scores, opioid dosages, and the length of hospital stay.[10–13] TAP block can block neural afferents of the T6-L1 spinal nerves innervating the anterolateral abdominal wall.[14] The posterior TAP block can block the lateral cutaneous branches of thoracolumbar spinal nerves (T9-L2), provide some degree of lateral abdominal wall analgesia, and may be more suitable for urological procedures.[15,16] During laparoscopic nephrectomy, factors such as gas distension of the abdominal wall, abdominal port placement, and retroperitoneal dissection can induce pain from T6-T12 somatic nerves and sympathetic innervation of the abdominal viscera and renal pelvis.[17–19] Notably, TAP block only generates analgesia of the abdominal wall and has a limited analgesic effect on visceral pain.

Recently, our research team reported a novel blockade technique, low thoracic paravertebral block (TPVB) via the arcuate ligament under direct visualization. The quadratus lumborum (QL) muscle originates from the iliac crest and the iliolumbar ligament, inserts on the surface of T12 rib and the transverse processes of L1-L4 vertebrae. The medial arcuate ligament arises at the anterolateral border of the L2 vertebral body, spans the psoas major muscle, and ends at the L1 transverse process. The lateral arcuate ligament spans from the L1 transverse process to the middle segment of the T12 rib. Collectively, the medial and lateral arcuate ligaments constitute the inferior border of the diaphragm. The thoracolumbar fascia is divided cephalad into two layers, one connected to the intrathoracic fascia and the other fused with the medial and lateral arcuate ligament. This anatomical configuration provides an important pathway for the diffusion of local anesthetic (LA) to the lower thoracic paravertebral space (T10-T12) through the medial and lateral arcuate ligaments, constituting the fundamental anatomical basis for this technique. These anatomical relationships are clearly demonstrable under direct laparoscopic visualization. Thus, under direct laparoscopic visualisation, the operator can inject the LA through the medial arcuate ligament into the dorsal aspect of the diaphragm (lower thoracic paravertebral space), thereby achieving somatic and visceral pain analgesia. The inherent tension of the medial arcuate ligament and needle tip orientation results the drug to diffuse primarily cephalad and medial. The dermatomal coverage of the sensory block is often between T6-7-L1-2.[20] This blockade technique has been successfully applied to patients undergoing retroperitoneal laparoscopic nephrectomy, demonstrating maintained low postoperative pain scores (at rest or movement) and opioid consumption.[21] During open or laparoscopic retroperitoneal nephrectomy, the integrity of the transverse fascia that encases the psoas major and psoas quadratus muscles may be damaged,[22,23] leading to leakage of LA within the fascial layer, which in turn affects the analgesic effect of the targeted blocked area. In contrast, this blockade technique

can confirm the integrity of the transverse fascia under direct vision, reduce the leakage of LA, and allow better diffusion of LA into the low thoracic paraspinal space.

Low TPVB via the arcuate ligament under direct visualization is simple and safe, importantly avoids injury to the donor kidney. Injecting drug under direct visualization can prevent damage to important organs, thereby reducing the risk of serious complications such as postoperative hematoma and intestinal injury etc. Intraoperative procedures can maintain strict sterility, minimizing the risk of cross-infection associated with contact from the ultrasound probe. Notably, the whole puncture procedure can be completed within a few minutes without special puncture consumables, reducing both anesthesia time and medical costs. This technique can anesthetize the spinal nerve roots and sympathetic chain in the paravertebral space, potentially providing more effective analgesia for somatic and visceral pain compared to the TAP block. However, no studies have compared the quality of postoperative recovery between the low thoracic paravertebral block via the arcuate ligament and TAP block in living kidney donors undergoing LDN. Therefore, this study will perform a prospective, randomized, controlled clinical trial aimed at comparing the quality of postoperative recovery between the two block techniques in living kidney donors. We hypothesize that low TPVB via the arcuate ligament under direct visualization will be more effective than TAP block in improving the quality of postoperative recovery within 24 hours in donors. With this study, we expect to guide the optimization of postoperative analgesic strategies, which in turn will promote the rapid recovery of living kidney donors.

Methods and Analysis

Trial Design

This study is a prospective, blind, randomized, controlled clinical trial with a concealed allocation of patients scheduled to undergo elective LDN 1:1 to receive either a low TPVB or a TAP block. The study started in December 2024, and the recruiting period will last 23 months. The trial will start to recruit patients after registered in the Chinese Clinical Trial Registry.

Eligibility Criteria

Donors will be considered eligible for enrollment if they fulfill all the inclusion criteria at screening and none of the exclusion criteria. In addition, donors are allowed to drop-out from the study at any time if they withdraw informed consent, loss to follow-up, do not collect the efficacy and safety data or are ordered to withdraw by investigators.

Inclusion Criteria

Gender unlimited, aged 18–70 years, ASA I–II, and planned to undergo elective LDN.

Exclusion Criteria

Preoperative use of anticoagulant medications; long-term use of analgesics; allergic to the drugs used in standardized anesthesia, or with severe cardiovascular or cerebrovascular diseases; history of drug or alcohol abuse; previous thoracic or spinal surgery and spinal deformity; inability to understand the QoR-15 score; infection at the puncture site; and refusal to participate in observation.

Participant Eligibility and Consent

The investigator will identify eligible patients based on the criteria listed. Eligible patients will receive written and verbal informed consent and will be included in the trial after investigators have obtained informed written consent.

Randomization and Blinding

A web-based randomizer (https://www.trialstats.com/statbox/) was used to generate a random number table by a researcher not involved in the study. The randomized numbers will be kept in the opaque sealed envelopes, which will be opened by two research assistants not involved in the study according to the prescribed principles when the patients meet the inclusion criteria, and the envelopes will be marked with the corresponding random number and group. Based on the randomization number, the patients will be divided at a 1:1 ratio into the two groups: the low TPVB group

and the TAP block group. In both groups, the block will be administered after anesthesia, and the patients are unaware of the block they received. The postoperative follow-up staff and patients are unaware of the study group allocation, and the follow-up staff did not intervene in the postoperative analgesic regimen.

Interventions

All enrolled patients will be assigned to one of the following two study groups:

► The posterior TAP block group: Patients will receive an operative lateral TAP block after the induction of anesthesia and before surgery.

The patients are placed in the full-flank, mid-lumbar flexion position. After routine abdominal disinfection, the high-frequency 8–13 MHz ultrasonic probe is placed posterior to the midaxillary line between the costal margin and the iliac crest. Using the in-plane needle insertion method, the needle is injected from the midaxillary line. The injection site is at the TAP between the internal oblique and transversus abdominis posterior to the midaxillary line and near the aponeurosis. 2 mL of 0.9% sodium chloride solution is injected to separate the plane, and the needle tip position is confirmed again. After no blood is withdrawn, 25 mL of 0.4% ropivacaine is injected.

►Low TPVB group: Patients receive a low TPVB via the arcuate ligament under direct visualization by the surgeon after obtaining the donor kidney before suturing the wound.

The block procedure is performed by the same group of operationally experienced surgeons who had performed more than 30 low TPVBs prior to the start of the study. The surgeon secures the trocar needle tip by operating forceps and punctures it cephalad from the midpoint of the inferior border of the medial arcuate ligament to the dorsal aspect of the diaphragm, with the direction of the puncture parallel to the midline of the spine and the puncture needle 15 degrees to the psoas major muscle. A small amount of 0.9% saline (2–5 mL) is given after the assistant has confirmed that there is no blood or cerebrospinal fluid, and when the fluid is seen spreading cephalad locally bulging and without resistance, 25 mL of 0.4% ropivacaine continues to be given. If the transversus fascia is damaged or incomplete on laparoscopic exploration, this patient will be excluded, and before extubation at the end of the operation, a TAP block will be performed under ultrasound guidance, and 25 mL of 0.4% ropivacaine will be given.

All patients receive routine monitoring, including electrocardiogram (ECG), heart rate (HR), non-invasive blood pressure (NIBP), pulse oxygen saturation (SpO_2), and bispectral index (BIS).

Anesthesia and Surgical Management

All participants received the same anesthetic management and surgical procedures in accordance with the standard protocols of our institution. General anesthesia induction: midazolam (0.02 mg/kg), sufentanil (0.3–0.4 μg/kg), propofol (2 mg/kg) and cisatracurium (0.2 mg/kg). After successful intubation, anesthesia was maintained with intravenous infusions of propofol (4–8 mg/kg/h) and remifentanil (0.1–0.3 μg/kg/min). The depth of anesthesia was monitored with the BIS, which was maintained between 40 and 60. The lungs of patients are mechanically ventilated via a volume-controlled model with a tidal volume of 6–8 mL/kg, positive end-expiratory pressure (PEEP) of 5 cmH_2O, 0.6 fraction of inspiration oxygen and respiratory rate of 12–18/min to maintain the $P_{ET}CO_2$ at 35–45 mmHg. Fifteen minutes before the end of surgery in both groups, sufentanil (5 μg) and tropansetron (5 mg) are given intravenously. Following surgery, neostigmine (40 μg/kg) and atropine (0.5 mg) are used to reverse neuromuscular blockade. The endotracheal tube will be removed when the patient regains spontaneous breathing and consciousness, after which the patient will be transferred to the postoperative anesthesia recovery room (PACU) for observation.

According to our routine practice,[24] the modified Hand-assisted retroperitoneoscopic living donor nephrectomy (HARPLDN) is used in all donor nephrectomies with patients in the full-flank, mid-lumbar flexion position. All donor nephrectomies will be performed by the same surgical team under carbon dioxide pneumoperitoneum with a pressure of 10–13 mmHg. A 2-cm incision is made in the midaxillary line, 2 cm above the superior border of the ilium. Then, 3 or 4 retroperitoneoscopic ports are placed in the posterior axillary line and anterior abdominal wall positions. Prior to transection of the renal artery, a 6–7 cm mini-open muscle-splitting incision is made at a position close to the inguinal canal, similar to a Gibson incision. The graft is extracted rapidly from this incision and flushed with iced perfusion solution.

Relevant Complications of Management During Anesthesia

If the mean arterial pressure (MAP) is <60 mmHg, dopamine (3 mg) is intravenously administered, and then continuously infused at a rate of 2–5 μg/kg/min if needed. If the heart rate (HR) is <50 beats/min, 0.5 mg of atropine is intravenously injected.

Postoperative Analgesia Treatment

Patients in both groups will use the patient-controlled intravenous analgesia (PCIA) with the following analgesic regimen: sufentanil 100 ug and ondansetron 16 mg in 0.9% sodium chloride of 100 mL, a single bolus dose of 2 mL with a lockout time of 10 min. Paracetamol (1 g) is given every 8 hours and flurbiprofen (50 mg) intravenously every 12 hours postoperatively. When the numerical rating scale (NRS) pain score is greater than 4 at rest, rescue medication is administered intravenously for pain relief (eg, 100 mg of tramadol in the PACU and 50 mg of flurbiprofen injection after transfer to the ward). No other types of analgesics or regional analgesic techniques are allowed.

Outcome Measures

Primary Outcome Measure

The primary outcome is the global score Quality of Recovery-15 scale (QoR-15) at 24 hours after surgery.[25,26]

Secondary Outcomes Measure

1. Patients' characteristics, anesthesia and surgery data.
2. The NRS score at rest and activity (when coughing, getting out of bed, or walking): the assessment time points include the preoperative day, arrival in the PACU, and at 2, 6, 12, 24 and 48 hours after surgery.
3. Time to the first opioid request (from arrival in the PACU until the first PCA bolus).
4. The intravenous morphine equivalent (IVME) doses consumed at 24 and 48 hours after surgery.
5. Use of rescue analgesics at 48 hours after surgery.
6. Postoperative adverse reactions such as nausea, vomiting, dizziness, skin itching, and adverse events related to nerve block operation.
7. Time to first postoperative discharge, time to first ambulation (from arrival in the PACU until the patient was able to stand on the floor and walk), time to removal of urinary catheter and drain, length of hospital stay, and postoperative complications (based on the Clavien–Dindo classification).[27]
8. Patient satisfaction score (1 = very satisfied, 2 = satisfied, 3 = unsatisfied, 4 = very unsatisfied).
9. Kidney function variables (glomerular filtration rate, serum urea nitrogen and creatinine).

Statistical Analysis and Sample Size Calculation

Quantitative data are presented as the mean (standard deviation, SD) or median (interquartile range, IQR). According to the normality of the data, which is confirmed by the Shapiro–Wilk test, their between-group comparisons will be performed using Student's *t* test or the *Mann–Whitney U*-test. Qualitative data are expressed as frequencies or percentages and the comparisons of between the intervention and control groups will be done using the *Chi-square* test or *Fisher's* exact test. The primary outcome of our study is the QoR-15 score, and the comparison of between-group will be checked using Student's *t* test or the *Mann–Whitney U*-test. Generalized estimating equations or ANVOA will be used to compare the between-group differences in the QoR-15 score at different time points. For all analyses, a two-sided $P < 0.05$ is considered to indicate statistical significance. The SPSS software 23.0 and GraphPad Prism 10.0 will be used for all the statistical analyses.

The sample size was calculated based on the primary outcome: the QoR-15 score at 24 h postoperatively. The minimum clinically important difference (MCID) for the QoR-15 score is 6[28] and the standard deviation is typically between 10–16 (range 1–150). According to the results of the pretest study, the difference of mean in QoR-15 score between the two groups was 8, with an SD of 12. Using an online program (https://www.trialstats.com/statbox/), assuming a power of 80% with an alpha of 0.05, we calculated that a sample size of 37 participants in each group was required. Considering a potential dropout rate of 10%, a final sample size of 82, ie, 41 participants in each group, was determined.

Ethical Considerations, Amendments and Dissemination

All kidneys will be donated voluntarily with written informed consent, and that these will be conducted in accordance with the Declaration of Istanbul. This trial is conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. The protocol was approved by the Ethics Committee of Beijing Friendship Hospital and registered at the Chinese Clinical Trial Registry (www.chictr.org.cn). Any significant modifications to the study protocol or significant modifications in other study documents which may affect the study, potential benefit or safety of patients, will be submitted for approval to the local medical ethical committee, and meanwhile require a formal amendment to the protocol. With respect to patient confidentiality and data protection measures, we anonymize or code subjects to avoid specific subjects being identified, and desensitize sensitive information, such as replacing sensitive words and removing personal identification information. We will train participating researchers in privacy awareness and skills, follow the principle of data minimization, and collect only the data necessary to accomplish the specific goals of the research. If data need to be shared, we ensure that the shared data are appropriately desensitized to protect the privacy of the subjects. When sharing data, numbers are used instead of personal identifiable information. It allows only authorized personnel to access and process the data to prevent unauthorized access. The results of this trial will be publicly disclosed, published in scientific journals or presented at scientific conferences, regardless of the outcome.

Trial Status

This trial was approved by the Ethics Committee of Beijing Friendship Hospital, Capital Medical University. This study protocol was approved on 30 November 2024. The trial started recruiting patients after registered in the Chinese Clinical Trial Registry.

Discussion

LDN has become the gold standard procedure for living kidney donors.[4] Even as nephrectomies move away from open procedures, laparoscopic cases are still associated with significant pain, with some studies showing no difference in pain or opioid demand between the two operations.[29,30] Moreover, nearly one-quarter of the donors experienced chronic pain or discomfort after surgery, most of whom were bothersome.[31] Donors who present with chronic pain have a greater probability of having a poor health-related quality-of-life (HRQoL) post donation.[32] The management of postoperative pain plays an important role in the recovery of laparoscopic living donor nephrectomy patients.[33,34] However, traditional analgesic methods have several disadvantages and risks, such as high requirements for coagulation function, slow onset of action, inaccurate results, and lack of visceral analgesia. Although ultrasound-guided techniques have improved the safety and efficacy of the regional block techniques,[35] there is still a risk of puncture-related complications and even damage to the donor organ in beginners or donors with anatomical abnormalities. To the best of our knowledge, this is the first prospective, randomized, controlled clinical trial to observe the use of low TPVB via the arcuate ligament under direct visualization by surgeons for living kidney donors undergoing LDN. In previous studies by our team, low TPVB was effective in reducing postoperative pain scores and reducing opioid consumption.[20] This technique is simple to perform, requires a short learning curve, and reduces the operative time without damaging the donor organ, making it worthy of clinical promotion. However, the effectiveness of this new technique in terms of perioperative application in donors is currently unclear; therefore, we conducted this study with the aim of providing more experience and evidence on postoperative pain management in living kidney donors.

Despite the careful design of this trial, there are still several limitations. First, although the QoR-15 questionnaire is a multidimensional patient-reported outcome that has been validated in the perioperative setting, it has undergone extensive psychometric validation and systematic review.[25,26] However, the questionnaire is highly influenced by patient subjectivity and suffers from subjective bias, such as response bias and recall bias. Thus, before the initiation of this trial, the investigator and site staff received systemic training for the use of these questionnaires and were certified to avoid subjective bias as much as possible. Before surgery, all patients were instructed on how to fill out the QoR-15 questionnaire. Moreover, in this trial, objective assessments, including postoperative opioid consumption, time to exhaustion, and length of hospital stay, will also be performed to assess the quality of postoperative recovery

comprehensively. Second, there is a lack of blinding to the anesthesiologist and the surgeon due to the different operators of blocks in the two groups. However, the block operation is completed after the induction of anesthesia in both groups; therefore, the patients, nurse anesthetists in the PACU, and follow-up physicians are unaware of the intervention assignment, eliminating differences in postoperative assessment to the greatest extent possible. Thirdly, performing the block at different stages does have the potential to introduce an element of bias. We minimize the time difference between the two blocks to reduce the bias.

Overall, the results of this study may have a practical and clinical advantages, and this study is a significant attempt to optimize the efficacy and safety of perioperative pain management in living kidney donors, which will provide a more precise, efficient, and safer analgesic management plan for donors.

Data Sharing Statement

All data used or analyzed in this study can be obtained from the corresponding authors.

Disclosure

The authors report no conflicts of interest in this work.

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