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Comparative analysis of two different kidney harvesting incisions after retroperitoneal laparoscopic nephrectomy in living donors

Submission date 26/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/12/2025	**Overall study status** Completed	
Last Edited 30/12/2025	**Condition category** Digestive System	

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration.

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Prospective randomized trial of abdominal versus lumbar extraction incisions after retroperitoneal laparoscopic left nephrectomy in living donors

Study objectives

This study was designed to address the critical knowledge gap regarding optimal extraction incision placement in retroperitoneal laparoscopic living donor nephrectomy. We hypothesized that abdominal extraction incisions would result in lower incisional hernia rates and reduced abdominal wall dysfunction compared to lumbar incisions, while maintaining equivalent graft outcomes and operative safety. Our primary objectives were to compare incisional hernia incidence and motor function deficits between techniques, with comprehensive assessment of pain trajectories, sensory outcomes, and long-term quality of life as secondary endpoints.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2024, The Ethics Committee of The First Affiliated Hospital of Henan University of Science and Technology (No. 24, Jinghua Road, Jianxi District, Luoyang, Henan, 471003, China; +86 0379-64922216; N/A), ref: 2024-03-K0088

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Optimal extraction incision placement in retroperitoneal laparoscopic living donor nephrectomy.

Interventions
This prospective, single-blind RCT involved living kidney donors who were randomized 1:1 to an abdominal diagonal or a lumbar horizontal extraction incision.

Randomization and Blinding
Participants were randomized in a 1:1 ratio to either the abdominal or lumbar extraction group using computer-generated block randomization with variable block sizes of 4, 6, and 8. Randomization was stratified by surgeon experience (junior with less than 50 prior retroperitoneal nephrectomies, or senior with 50 or more procedures) and operative side (left or right kidney). Randomization was stratified by surgeon experience (junior with less than 50 prior retroperitoneal nephrectomies, or senior with 50 or more procedures). All nephrectomies were

performed on the left side; right-sided donations were excluded during screening (see Participant Selection). The allocation sequence was generated by an independent statistician and concealed using sequentially numbered, opaque, sealed envelopes that were opened in the operating room immediately before incision placement. Given the nature of the surgical intervention, surgeons and operating room personnel could not be blinded to group allocation. However, all postoperative assessments were performed by trained research nurses and physiotherapists who remained blinded to the extraction technique throughout the study period. Blinding was ensured by standardizing surgical dressings to conceal the incision location, and patients were instructed not to discuss surgical details with assessors. Surgical dressings were standardized to conceal incision location during early postoperative evaluations. The biostatistician performing the primary analysis remained blinded until database lock.

Surgical Standardization

All procedures were performed under general anesthesia with endotracheal intubation using a standardized anesthetic protocol that included preoperative multimodal analgesia with acetaminophen 1000 mg and celecoxib 200 mg orally. Intraoperative remifentanil infusion was titrated to maintain hemodynamic stability, with a mean total dose of 0.15 ± 0.04 mcg/kg/min (total cumulative dose per patient: 18.6 ± 4.2 mcg/kg based on median operative time of 143 minutes).

Local anesthetic infiltration with 0.25% bupivacaine (total volume: 15 ± 3 mL) was performed at all port sites before incision, with equal distribution (5 mL per port site) to ensure uniform analgesic coverage of the surgical access areas. The retroperitoneal space was established using the balloon dissection technique, with the patient positioned in lateral decubitus with the operative side elevated. Three trocars were placed in standardized locations: the primary 12-mm camera port 2 cm above the iliac crest at the mid-axillary line, a 5-mm port at the anterior axillary line below the costal margin, and a 5-mm port at the posterior axillary line.

Pneumoretroperitoneum was maintained at 12-14 mmHg using CO_2 insufflation. The surgical dissection followed a systematic approach beginning with the identification of the psoas muscle and ureter, followed by isolation of the gonadal vessels and subsequent identification of the renal hilum. The renal artery was secured with three Hem-o-lok clips and divided, followed by similar management of the renal vein. The ureter was clipped and divided as distally as possible while maintaining adequate length for recipient implantation. Throughout the procedure, meticulous attention was paid to preserving perirenal fat and avoiding capsular trauma. For kidney extraction in the abdominal incision group, the anterior 5-mm port incision was extended diagonally toward the umbilicus to create a 5-6 cm muscle-splitting incision through the external oblique, internal oblique, and transversus abdominis muscles. The incision was oriented parallel to the dermatomal distribution to minimize nerve transection. In the lumbar incision group, the posterior 5-mm port was extended horizontally in a ventral direction, creating a 5-6 cm incision through the latissimus dorsi and underlying musculature.

Standardized closure techniques were employed for both groups. The fascial layers were closed with continuous 1-0 polydioxanone sutures, ensuring adequate tissue purchase without excessive tension. Subcutaneous tissues were approximated with interrupted 2-0 polyglactin sutures, and skin closure was achieved with 3-0 poliglecaprone subcuticular sutures. No prophylactic mesh reinforcement was used in either group. A closed-suction drain was placed through the camera port site and removed when output was less than 30 mL per 24 hours.

Postoperative Management Protocol

Postoperative analgesia followed a standardized multimodal protocol designed to minimize opioid exposure while ensuring adequate pain control. The regimen included scheduled acetaminophen 1000 mg every 6 hours, ketorolac 30 mg every 8 hours for 48 hours (with renal function monitoring), and patient-controlled analgesia with morphine (1 mg bolus, 8-minute

lockout, no basal rate) for breakthrough pain. Transition to oral analgesics occurred when patients tolerated oral intake, typically within 24 hours.

Early mobilization was encouraged with patients ambulating within 6 hours postoperatively when hemodynamically stable. Progressive activity advancement followed a structured protocol with specific daily goals. Dietary advancement proceeded from clear liquids to regular diet as tolerated, with antiemetic prophylaxis using ondansetron and dexamethasone. Thromboprophylaxis consisted of sequential compression devices and early ambulation, with pharmacologic prophylaxis reserved for high-risk patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Incisional hernia development measured using ultrasound examination at 12 months after the operation

Key secondary outcome(s))
1. Total opioid consumption within the first 72 hours, calculated as morphine milligram equivalents measured using data collected from patient medical records at one time point

2. Surgical and Safety Outcomes, assessed through mean operative time measured using data collected from patient medical records at one time point

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Body mass index (BMI) between 18.5 and 29.9 kg/m². The BMI upper limit of 29.9 kg/m² was selected to minimize confounding from obesity-related complications such as hernia and wound healing issues, while maintaining generalizability.
3. Estimated glomerular filtration rate greater than 80 mL/min/1.73m²
4. American Society of Anesthesiologists (ASA) physical status classification I or II

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex

All

Total final enrolment
240

Key exclusion criteria
1. Previous major abdominal or retroperitoneal surgery
2. Known abdominal wall hernia or significant diastasis recti, chronic pain syndromes requiring regular analgesic use
3. Neuromuscular disorders affecting abdominal wall function
4. Active psychiatric conditions that could impact pain perception or reporting
5. Pregnancy or plans for pregnancy within the study period
6. Any contraindication to retroperitoneal laparoscopic surgery
7. Donors with variant renal anatomy requiring extensive dissection or those requiring right-sided nephrectomy were excluded to maintain procedural homogeneity
8. Right-sided nephrectomies were excluded to maintain procedural homogeneity and minimize anatomical variability, as the right kidney presents distinct surgical challenges

Date of first enrolment
01/03/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
China

Sponsor information

Organisation
First Affiliated Hospital of Henan University of Science and Technology

ROR
https://ror.org/035zbbv42

Funder(s)

Funder type

Funder Name
First Affiliated Hospital of Henan University of Science and Technology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date