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Exploring a new pain relief method for older adults having hip fracture surgery

Submission date
13/10/2025

Recruitment status
No longer recruiting

Registration date
08/12/2025

Overall study status
Completed

Last Edited
20/10/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Hip fractures are common in elderly people and often require surgery. However, older patients usually have other health problems that make anesthesia risky. Spinal anesthesia is commonly used but can cause drops in blood pressure and other side effects. This study aims to find out whether a combination of two types of ultrasound-guided nerve blocks — the supra-inguinal fascia iliaca compartment block (FICB) and the sacral plexus block (SPB) — can provide a safer and more stable anesthesia method compared with spinal anesthesia for elderly patients having hip fracture surgery.

Who can participate?
Elderly patients aged 65 years or older who are scheduled for hip fracture surgery at Dongyang People's Hospital can take part. Participants must be in American Society of Anesthesiologists (ASA) class II–III and able to give written informed consent. Patients will not be able to join if they have multiple fractures, severe organ problems, mental disorders, or any medical reason that makes nerve block anesthesia unsafe (such as bleeding disorders or infection at the injection site).

What does the study involve?
This is a randomised controlled trial. Participants will be randomly assigned to one of two groups: The FICB + SPB group, who will receive ultrasound-guided nerve blocks using local anaesthetic around the nerves of the hip and thigh.

The spinal anesthesia group, who will receive standard spinal anesthesia using local anaesthetic injected into the lower back.

All patients will receive the same postoperative pain control through a patient-controlled analgesia pump. Doctors will monitor blood pressure, heart rate, and oxygen levels during surgery, and assess pain levels and side effects after surgery. The study will compare the two groups to see which anesthesia method provides better pain control and fewer complications.

What are the possible benefits and risks of participating?
Participants in the combined nerve block group may experience more stable blood pressure and

better pain relief after surgery. They may also need fewer painkillers and have fewer side effects, such as nausea or constipation.
Possible risks include mild pain or bruising at the injection site, temporary numbness or weakness, or, rarely, infection or nerve injury. All procedures will be performed under ultrasound guidance by experienced anesthesiologists to reduce these risks.

Where is the study run from?
The study is being conducted at Dongyang People's Hospital, Zhejiang Province, China.

When is the study starting and how long is it expected to run for?
The study is expected to run from June 2024 to June 2025, including patient recruitment, surgery, and data collection.

Who is funding the study?
This study was supported by The Science and Technology Plan Project of Dongyang [grant numbers: 21-325].

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2023-YX-472

Study information

Scientific Title
Efficacy and safety of combined ultrasound-guided supra-inguinal fascia iliaca compartment block and sacral plexus block in elderly patients undergoing hip fracture surgery

Acronym
SITSP

Study objectives
This study aimed to evaluate the effectiveness and safety of combined ultrasound-guided supra-inguinal fascia iliaca compartment block (FICB) and sacral plexus block (SPB) compared with spinal anesthesia (SA) in elderly patients undergoing hip fracture surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/01/2024, Dongyang People’s Hospital (No. 60, Wuning West Road, Wuning Sub-district, Dongyang City, Zhejiang Province, Dongyang, 322100, China; +86 579-86815778; 15057996996@163.com), ref: 2023-YX-472

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Elderly patients undergoing hip fracture surgery

Interventions

FICB+SPB group: With the patient in the supine position, standard skin disinfection were performed. A high-frequency linear array transducer (S-Nerve, SonoSite Inc., USA) was placed perpendicular to the inguinal ligament, above the junction of the medial one-third and lateral two-thirds of the line connecting the anterior superior iliac spine and the pubic tubercle. The "hourglass-pattern" sign formed by the sartorius muscle, internal oblique muscle, and iliopsoas muscle, was identified 15. The fascia iliaca was visualized as a hyperechoic line overlying the iliopsoas muscle. After local infiltration with 1% lidocaine, an in-plane needle insertion technique was used to puncture the fascia iliaca. Following negative aspiration, 1-2 mL of normal saline was injected to confirm proper needle placement, indicated by separation between the fascia iliaca and the iliopsoas muscle and cranial spread of the injectate. Once the needle tip was verified to be correctly positioned, 40 mL of 0.25% ropivacaine (AstraZeneca AB) was slowly administered. After performing the supra-inguinal FICB, the patient was positioned in the lateral decubitus position with the affected limb uppermost to facilitate the SPB. A low-frequency convex array transducer was placed at the midpoint of the line connecting the posterior superior iliac spine and the greater trochanter. Under ultrasound guidance, the sacral plexus appeared as an oval hyperechoic structure located between the sacrum and the ilium. After local infiltration of 1% lidocaine at the puncture site, an in-plane needle insertion was performed from lateral to medial under real-time ultrasound visualization. The needle was advanced through the piriformis muscle to reach the sacral plexus. Once needle placement was confirmed and negative aspiration for blood was obtained, 20 mL of 0.25% ropivacaine (AstraZeneca AB) was slowly injected.

SA group: Intravenous infusion of dexmedetomidine at a dose of 0.5 μg/kg was administered prior to spinal anesthesia. The L2-3 or L3-4 interspace was identified for a combined spinal-epidural technique, using a Crawford epidural needle and a 22-G catheter (Spinocath®, B. Braun, Melsungen, Germany) combined with a 27-G Quincke spinal needle. Following successful dural puncture, 2.5 mg of 0.5% isobaric bupivacaine was injected into the subarachnoid space. The epidural catheter was then inserted and secured. To establish the desired anesthetic level, 3 mL of 2% lidocaine was administered through the catheter. If necessary, 0.5% ropivacaine was additionally injected via the epidural catheter to prolong the duration of anesthesia.

Total duration of treatment and follow-up:
The interventions (FICB + SPB or SA) were administered once, immediately before surgery. The total follow-up duration for all participants was 48 hours postoperatively, during which pain scores, analgesic consumption, and complications were assessed.

Randomisation process:
Patients were randomly assigned in a 1:1 ratio to either the FICB + SPB group or the SA group using a computer-generated randomization sequence created via an online tool (https://www.randomizer.org). The allocation sequence was concealed in sealed, opaque envelopes, which were opened by the attending anesthesiologist immediately before anesthesia administration.

Blinding:
The data collection and postoperative assessments were performed by two independent specialists blinded to the group allocation.
However, the patients and anesthesiologists were aware of the allocated intervention due to the nature of the anesthesia techniques.

Intervention Type

Procedure/Surgery

Primary outcome(s)
1. Hemodynamic response to surgical stress: Mean arterial pressure (MAP), systolic blood pressure (SBP), heart rate (HR), and oxygen saturation (SpO_2) were continuously monitored using standard noninvasive monitors. Measurements were recorded at six standardized timepointsT0: Before anesthesia; T1: At the time of skin incision; T2: 30 minutes after the start of surgery; T3: During key surgical steps; T4: At the end of surgery; T5: Upon leaving the operating room
2. Severity of postoperative pain: Pain intensity was assessed using the Visual Analog Scale (VAS, 0–10; 0 = no pain, 10 = worst pain imaginable). Pain was evaluated both at rest and during passive limb movement at 3, 6, 12, 18, and 24 hours postoperatively. Movement pain assessment: Passive mobilization was performed by gently elevating the injured limb approximately 15°

Key secondary outcome(s))
1. Postoperative sufentanil consumption is measured using cumulative dosage recorded from patient-controlled analgesia (PCA) device at 3, 6, 12, 18, and 24 hours postoperatively
2. Length of hospital stay is measured using electronic medical records at discharge
3. Anesthesia-related complications are measured using clinical observation and documentation in patient charts during the intraoperative and postoperative period until discharge
4. Mean arterial pressure (MAP) is measured using non-invasive blood pressure monitoring at T0 (before anesthesia), T1 (skin incision), T2 (30 minutes after surgery began), T3 (during key surgical steps), T4 (end of surgery), and T5 (upon leaving the operating room)
5. Systolic blood pressure (SBP) is measured using non-invasive blood pressure monitoring at T0, T1, T2, T3, T4, and T5
6. Heart rate (HR) is measured using electrocardiographic monitoring at T0, T1, T2, T3, T4, and T5
7. Peripheral capillary oxygen saturation (SpO2) is measured using pulse oximetry at T0, T1, T2, T3, T4, and T5
8. Postoperative pain at rest is measured using the Visual Analog Scale (VAS, 0–10) at 3, 6, 12, 18, and 24 hours postoperatively
9. Postoperative pain during passive movement is measured using the Visual Analog Scale (VAS, 0–10) during elevation of the injured limb approximately 15° at 3, 6, 12, 18, and 24 hours postoperatively

Completion date
20/08/2025

Eligibility

Key inclusion criteria
1. Patients diagnosed with first hip fracture confirmed by computed tomography and X-ray
2. Age ≥ 65 years
3. American Society of Anesthesiologists (ASA) physical status II–III
4. Provided written informed consent after fully understanding the anesthesia procedures, potential complications, and related precautions

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
65 years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Multiple fractures, such as pathological fractures, pelvic fractures, femur fractures
2. Long-term use of analgesic medications
3. Contraindications to peripheral nerve blocks, such as allergy to local anaesthetics, infection at the puncture site, lumbar degenerative disease, coagulopathy or bleeding disorders
4. Severe dysfunction of vital organs, including the cardiovascular or cerebrovascular systems
5. History of neurological, psychiatric disorders, or cognitive impairment

Date of first enrolment
01/06/2024

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
China

Study participating centre
Dongyang People’s Hospital
No. 60, Wuning West Road, Wuning Sub-district, Dongyang City, Zhejiang Province
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Sponsor information

Organisation
Dongyang People's Hospital

ROR
https://ror.org/04fszpp16

Funder(s)

Funder type
Government

Funder Name
The Science and Technology Plan Project of Dongyan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from the corresponding investigator.
Data availability plan:
Contact: Dr. Min Wang, Department of Anesthesiology, Dongyang People's Hospital
Email: wangmin13566726395@163.com
Type of data to be shared: De-identified individual participant data, including demographic information, anesthesia details, hemodynamic parameters, postoperative pain scores, and adverse event data.
Availability period: Data will be available after publication of the main results and will remain accessible for five years thereafter.
Access criteria: Data will be shared with qualified researchers for the purpose of secondary analyses related to perioperative anesthesia safety and pain management in elderly surgical patients. Requests will be reviewed and approved by the study ethics committee to ensure compliance with data protection and participant consent regulations.
Anonymisation: All shared datasets will be fully de-identified to protect participant confidentiality

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes