Study protocol and statistical analysis plan

Ultrasound guided pericapsular nerve group block in total hip arthroplasty

Study Protocol

Official Study Title: Efficacy of Ultrasound-Guided Pericapsular Nerve Group Block

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Study site: Sivas Cumhuriyet University Faculty of Medicine Hospital, Sivas, Türkiye

Responsible investigator in the ethics decision: Prof. Dr. İclal Özdemir Kol, Department of Anesthesiology and Reanimation

Ethics approval: Cumhuriyet University Clinical Research Ethics Committee, decision 2021-06/11, dated 1 June 2021

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Study Objective

The primary objective was to compare cumulative intravenous morphine consumption during the first 24 postoperative hours between patients receiving an ultrasound-guided pericapsular nerve group (PENG) block with bupivacaine and those receiving an ultrasound-guided normal saline injection into the same anatomical plane, in adults undergoing elective primary total hip arthroplasty under general anesthesia.

Study design and participants

Design and Study Period

This was a single-center, prospective, randomized, double-blind, sham-controlled trial with two parallel groups, conducted at Sivas Cumhuriyet University Faculty of Medicine Hospital in Sivas, Türkiye. Forty eligible patients were randomly allocated in a 1:1 ratio to receive either an ultrasound-guided pericapsular nerve group (PENG) block with bupivacaine (n = 20) or an ultrasound-guided normal saline injection into the same anatomical plane (n = 20).

Eligibility

Eligible participants were adults aged 20–80 years with American Society of Anesthesiologists (ASA) physical status I–III who were scheduled to undergo elective primary total hip arthroplasty for degenerative coxarthrosis under general anesthesia. Written informed consent was obtained from all participants before enrollment.

Patients with ASA physical status IV, anatomical abnormalities resulting from developmental dysplasia of the hip, previous hip surgery, or multiple trauma were excluded. Patients undergoing arthroplasty for femoral neck fracture and those who declined participation were also excluded.

Allocation and Masking

Participants were randomly assigned in a 1:1 ratio using 40 sequentially numbered, sealed, opaque envelopes containing 20 allocations to each study group. The envelopes were prepared and shuffled before enrollment by an anesthesia resident who was not involved in participant recruitment, block performance, perioperative management, or postoperative outcome assessment.

Study solutions were prepared by an anesthesiologist who was not involved in postoperative data collection. Participants and the anesthesiologist responsible for postoperative outcome assessment were blinded to group allocation.

Ethics and consent

Ethics approval for the trial was granted by the Cumhuriyet University Clinical Research Ethics Committee on 1 June 2021 (Decision No. 2021-06/11). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment.

Study Procedures and Interventions

Perioperative Management

All patients underwent routine preoperative anesthesia assessment and fasted for at least 8 hours before surgery. Crystalloid infusion was administered at 2 mL/kg/h during fasting, and intramuscular midazolam 70 micrograms/kg was given as premedication. Standard monitoring included electrocardiography, heart rate, mean arterial pressure, and peripheral oxygen saturation.

General anesthesia was induced with intravenous fentanyl 1 microgram/kg, propofol 2–3 mg/kg, and rocuronium 0.6 mg/kg. Anesthesia was maintained with 2% sevoflurane in a mixture of 50% oxygen and 50% air. At the end of surgery, intravenous sugammadex 4 mg/kg was administered to reverse neuromuscular blockade.

PENG Block and Control Injection

Following induction of general anesthesia and before surgical incision, patients were positioned supine. A low-frequency convex ultrasound transducer operating at 2–5 MHz was placed over the anterior inferior iliac spine and rotated approximately 45 degrees to align with the pubic ramus. The iliopubic eminence, iliopsoas muscle and tendon, femoral artery, and pectineus muscle were identified. A 22-gauge, 100-mm needle was advanced using an in-plane lateral-to-medial approach toward the plane between the iliopubic eminence and the psoas tendon. Following negative aspiration, a 2-mL saline test injection was administered to confirm needle placement. Patients in the PENG group received bupivacaine 1 mg/kg with 0.9% sodium chloride, whereas patients in the control group received 0.9% sodium chloride alone. The total injected volume in each group was 30 mL, including the 2-mL saline test injection. Injectate spread was observed under ultrasound guidance.

Surgery and Postoperative Care

All patients underwent cementless total hip arthroplasty through a posterior approach, performed by the same orthopedic surgeon. No periarticular, intra-articular, or incisional local anesthetic infiltration was administered. Physiotherapist-supervised mobilization with a walker began on the first postoperative day, with full weight bearing as tolerated.

Both groups received intravenous morphine through a patient-controlled analgesia (PCA) device. Morphine was prepared at a concentration of 0.5 mg/mL. The device delivered a 0.5-mg bolus with a 10-minute lockout interval, a maximum of six boluses per hour, and no background infusion.

Rescue analgesia was administered when the visual analog scale (VAS) pain score exceeded 5 and consisted of intravenous tramadol 100 mg and intravenous paracetamol 1000 mg. Apart from fentanyl administered during induction of general anesthesia, no scheduled systemic analgesic adjuncts were administered during the perioperative study period.

Participants were followed for analgesic and safety outcomes throughout the first 24 postoperative hours.

Outcome definitions and assessment schedule

The primary outcome was cumulative intravenous morphine consumption during the first 24 postoperative hours. Postoperative assessments were performed at 1, 2, 3, 4, 8, 16, and 24 hours. Patient satisfaction was assessed once, at postoperative hour 24.

Outcome	Measurement	Assessment period
Primary outcome — Cumulative morphine consumption	Total intravenous morphine delivered through the PCA pump, measured in milligrams.	First 24 postoperative hours;
Pain intensity	Pain assessed using a 10-cm visual analog scale, where 0 represented no pain and 10 represented the worst imaginable pain.	Postoperative hours 1, 2, 3, 4, 8, 16, and 24.
First rescue analgesia	Time to the first administration of rescue analgesia, measured in hours.	First 24 postoperative hours.
Rescue analgesia requirement	Number and percentage of participants receiving rescue analgesia.	First 24 postoperative hours.
Nausea	Presence or absence of postoperative nausea.	Scheduled assessments during the first 24 postoperative hours.
Vomiting	Presence or absence of postoperative vomiting.	Scheduled assessments during the first 24 postoperative hours.
Constipation	Presence or absence of postoperative constipation.	Scheduled assessments during the first 24 postoperative hours.
Heart rate	Heart rate in beats per minute.	Postoperative hours 1, 2, 3, 4, 8, 16, and 24.
Mean arterial pressure	Mean arterial pressure in mmHg.	Postoperative hours 1, 2, 3, 4, 8, 16, and 24.
Patient satisfaction	Satisfaction assessed using four ordered categories: poor, fair, good, and very good.	Postoperative hour 24.

Demographic characteristics, ASA physical status, operative duration, and block procedure duration were also recorded.

Statistical Analysis Plan

Study Objective and Treatment Comparison

The objective was to compare postoperative analgesic outcomes between adults undergoing elective primary total hip arthroplasty under general anesthesia who received ultrasound-guided pericapsular nerve group (PENG) block with bupivacaine and those who received an injection of normal saline at the same anatomical site.

Participants were randomized in a 1:1 ratio to two parallel groups:

- **PENG group:** Bupivacaine 1 mg/kg with 0.9% sodium chloride.
- **Control group:** 0.9% sodium chloride alone.

The total injected volume was 30 mL in each group, including the 2-mL saline test injection. Both groups received the same postoperative intravenous morphine patient-controlled analgesia regimen.

The principal treatment comparison concerned cumulative intravenous morphine consumption during the first 24 postoperative hours.

Analysis Population

The study included 40 randomized participants, with 20 participants in the PENG group and 20 participants in the control group.

All 40 participants completed the 24-hour postoperative follow-up and were included in the final analysis. No participant was lost to follow-up, and no participant discontinued the allocated intervention.

The individual participant was the unit of analysis. Repeated postoperative measurements represented observations obtained from the same participant at different assessment times.

General Statistical Methods

Continuous variables were summarized as means and standard deviations. Categorical variables were summarized as frequencies and percentages.

Between-group comparisons of continuous variables were performed using independent-samples t-tests. Between-group comparisons of categorical variables were performed using chi-square tests. Changes in repeatedly measured continuous variables over time were evaluated using repeated-measures analysis of variance (ANOVA).

All statistical tests were two-sided. A P-value below 0.05 was considered statistically significant.

Demographic and Perioperative Characteristics

Demographic and perioperative characteristics were summarized separately for each study group.

Continuous characteristics included age, body weight, height, operative duration, and block procedure time. Categorical characteristics included sex and American Society of Anesthesiologists (ASA) physical status.

Continuous characteristics were presented as means and standard deviations and compared using independent-samples t-tests. Categorical characteristics were presented as frequencies and percentages and compared using chi-square tests.

These characteristics described the study population and the perioperative context of the treatment comparison.

Primary Outcome

The primary outcome was cumulative intravenous morphine consumption during the first 24 postoperative hours, expressed in milligrams.

Morphine was administered through an intravenous patient-controlled analgesia device in both groups. The morphine concentration was 0.5 mg/mL, with a bolus dose of 0.5 mg, a lockout interval of 10 minutes, a maximum of six boluses per hour, and no background infusion.

The primary outcome represented intravenous morphine consumption. Rescue analgesic requirements were assessed separately.

Cumulative 24-hour morphine consumption was summarized as the mean and standard deviation for each group. The between-group comparison was performed using an independent-samples t-test.

For this comparison, the null hypothesis was that mean cumulative 24-hour morphine consumption was equal between the groups. The two-sided alternative hypothesis was that the group means differed.

Lower cumulative morphine consumption indicated a lower postoperative morphine requirement.

Repeated Measurements of Morphine Consumption

Cumulative morphine consumption was recorded at postoperative hours 1, 2, 3, 4, 8, 16, and 24.

Measurements at each assessment time were summarized separately for the PENG and control groups as means and standard deviations. Between-group comparisons at individual assessment times used independent-samples t-tests.

Repeated measurements over the postoperative observation period were evaluated using repeated-measures ANOVA.

The earlier measurements described the postoperative pattern of morphine consumption. Cumulative consumption at postoperative hour 24 remained the primary outcome.

Postoperative Pain Intensity

Postoperative pain intensity was assessed using a 10-cm visual analog scale (VAS), with 0 representing no pain and 10 representing the worst imaginable pain.

VAS assessments were performed at postoperative hours 1, 2, 3, 4, 8, 16, and 24.

Pain scores were summarized as means and standard deviations for each group at each assessment time. Between-group comparisons at individual assessment times were performed using independent-samples t-tests.

Repeated postoperative pain measurements were evaluated using repeated-measures ANOVA. Lower VAS scores indicated lower pain intensity.

Rescue Analgesic Requirement

Rescue analgesia was administered when the VAS pain score exceeded 5. Rescue treatment consisted of intravenous tramadol 100 mg and intravenous paracetamol 1000 mg.

Rescue analgesic requirement was evaluated as a categorical outcome indicating whether a participant received rescue analgesia during the first 24 postoperative hours.

The number and percentage of participants requiring rescue analgesia were summarized separately for each group. The between-group comparison was performed using a chi-square test.

Time to first rescue analgesia was recorded in hours and reported separately from the proportion of participants requiring rescue treatment. The reported analysis summarized this time as a mean and standard deviation and used an independent-samples t-test for the between-group comparison.

Postoperative Hemodynamic Outcomes

Postoperative heart rate and mean arterial pressure were recorded at postoperative hours 1, 2, 3, 4, 8, 16, and 24.

Heart rate was expressed in beats per minute, and mean arterial pressure was expressed in millimeters of mercury.

Each variable was summarized as the mean and standard deviation for each group at each assessment time. Between-group comparisons at individual assessment times were performed using independent-samples t-tests.

Repeated postoperative measurements were evaluated using repeated-measures ANOVA.

Postoperative Adverse Events

Postoperative nausea, vomiting, and constipation were recorded during the first 24 postoperative hours. These events were assessed at the scheduled postoperative observation times.

Each adverse event was summarized separately as the number and percentage of participants experiencing the event during follow-up.

Between-group comparisons of categorical adverse event outcomes used chi-square tests. Outcomes with no observed events in either group were presented descriptively without a between-group P-value.

Block-related complications were also summarized descriptively by treatment group.

Patient Satisfaction

Patient satisfaction was assessed once, at postoperative hour 24, using four ordered response categories:

- Poor
- Fair
- Good
- Very good

Satisfaction responses were summarized as frequencies and percentages within each category for each treatment group.

Satisfaction was treated as a categorical outcome. Between-group comparisons followed the chi-square approach used for categorical variables.

The four response categories were retained in the descriptive presentation.

Presentation of Analyses

The primary outcome, secondary outcomes, and adverse events were presented separately.

For repeatedly measured outcomes, the scheduled postoperative assessment times were identified explicitly. Group summaries were presented for each assessment time alongside the corresponding between-group comparisons.

Continuous outcomes were reported in their original measurement units. Categorical outcomes were reported as participant counts and percentages.

The presentation distinguished the cumulative 24-hour morphine outcome from the earlier postoperative measurements and distinguished the occurrence of rescue analgesia from the time to first rescue treatment.

Statistical Software

Statistical analyses were performed using IBM SPSS Statistics, version 23.0 (IBM Corp., Armonk, New York, USA).

All statistical tests were two-sided, and a P-value below 0.05 was considered statistically significant.