Comparison of the Efficiency of Femur Nerve Block and Intravenous Analgesia Treatment in Hip Fracture Patients

MATERIALS AND METHODS

Design and Setting

This was a prospective, double-blind, randomized, single-center superiority trial with a 1:1 parallel-group design, conducted in an academic ED. Ethical approval for this study was obtained from the local ethics committee and the institutional review board (approval no: 09.2022.604, Marmara University Faculty of Medicine Clinical Research Ethics Committee). The study was conducted in accordance with the ethical standards of the Declaration of Helsinki and relevant local regulations. We used the CONSORT checklist when writing our report.

Study Population, Inclusion, and Exclusion Criteria

All consecutive adult patients (aged ≥18 years) presenting to our ED between November 2022 to December 2024 with a radiologically verified hip fracture were screened for inclusion based on the following criteria: (i) diagnosed with a unilateral fracture of the femoral neck or proximal femur via radiological evaluation; (ii) provision of informed consent by the patient, a relative, or a legal guardian.

The exclusion criteria were as follows: (i) hemodynamic instability or requiring urgent intervention for trauma; (ii) concomitant fractures; (iii) INR ≥2.5 or at risk of hemorrhage; (iv) received analgesics or a nerve block to the affected area prior to arrival at the ED; (v) allergy to local anesthetic agents or fentanyl; (vi) pregnancy; (vii) periprosthetic fracture; (viii) peripheral neuropathy.

Randomization and Allocation Concealment

Patients who met the inclusion/exclusion criteria were enrolled and randomly assigned in a 1:1 ratio to receive either FNB or fentanyl therapy. Randomization was performed using a computer-generated sequence with blocks of six to ensure a balanced allocation of groups. The allocation sequence of patients was concealed using consecutively numbered and sealed envelopes. A non-blinded investigator performed the randomization.

Masking

In accordance with the methodology of the study, the attending physician, nurses, treatment team, and participants were blinded using the following protocol:

To blind the treatment allocation, each participant was administered intravenous (IV) treatment and femoral nerve injection concurrently, with one group receiving a placebo in lieu of the IV analgesic and the other group receiving a placebo in place of the FNB. FNB was administered as 20 mL of 0.5% bupivacaine or a placebo (20 mL of 0.9% normal saline) filled into a syringe. The intravenous analgesic was administered as fentanyl at a dosage of 1 mcg/kg. (This was created by drawing 100 mcg of fentanyl into the syringe and diluting it with 100 mL of 0.9% sodium chloride solution.) The placebo consisted 100 mL of 0.9% normal saline solution.
Syringes and serum set for FNB and IV treatment were prepared by a non-blinded investigator according to the instructions. The syringes were labeled with the designations "Syringe A" and "Syringe B," while the serum sets were labeled "Set A" and "Set B." Syringes and sets prepared with application instructions were given to the team administering the treatment according to the randomization order (A or B). The application instructions delineated the protocol for the administration of FNB and IV treatment, enumerating the sequence in which the respective procedures were to be executed. For example, "Initially, administer the medication in syringe B for FNB." Administer the drug in Set B for intravenous analgesic treatment at a dosage of 1 cc per kilogram to the patient.

Data Collection

Vital signs, chronic diseases and demographic data about the patients were documented at the time of admission. Pain scores were recorded by nurses, blinded to the treatment groups, just before to the initiation of therapy and 20 minutes post-treatment completion.

Cognitive functions of participants were evaluated utilizing the Glasgow Coma Scale (GCS) and the Abbreviated Mental Test 4 (AMT-4). The Numeric Pain Rating Scale (NPRS) was employed for patients capable of verbally rating their pain (GCS was 15 and AMT-4 ≥8) on a scale of 0 to 10, whilst the Pain Assessment in Advanced Dementia Scale (PAINAD) was utilized to evaluate pain in individuals with cognitive impairment (GCS <15 or AMT-4 <8). This guaranteed that all participants obtained a uniform score ranging from 0 to 10.

We also followed whether patients needed rescue analgesia (IV fentanyl, tramadol or morphine) within four hours after the end of treatment.

FNB procedure

The femoral nerve block (FNB) was performed by three researchers who had training in this domain and a minimum of two years of practical experience in its implementation.

Patients were placed in the supine position. Following preparation and the administration of local anesthesia, 20 mL of 0.5% bupivacaine or 20 mL of 0.9% normal saline as a placebo was injected into the region utilizing a high-frequency linear probe under ultrasound guidance. The nerve was recognized as an echogenic triangular region lateral to the femoral vein. An ultrasonic needle sized 22G x 50 mm (SonoPlex STIM; PAJUNK GmbH, Geisingen, Germany) was placed by the Seldinger technique until its tip was positioned near to the femoral nerve. Following the confirmation of negative aspiration, a small-volume injection was administered, and the expansion of the nerve sheath was visualized on the monitor as the fluid infused. Subsequently, the entire 20 mL was administered to finalize the treatment. Throughout the

process, blood pressure, heart rate, respiration rate, and arterial oxygen saturation were observed.

Outcomes

The primary outcome of the study was the change in pain intensity from baseline to 20 minutes after the intervention. The secondary outcomes included the need for rescue analgesia and the occurrence of adverse events.

Sample size estimation

The sample size was calculated to obtain a statistically significant difference between the two groups in the change in the pain scale at 20 minutes after treatment, which was our primary endpoint in comparing the analgesic efficacy of FNB and IV opioids in patients with hip fractures. To demonstrate this difference with 90% power, we determined the sample size to be 52 for each group, totaling 104, based on calculations from previous studies. Calculations were made with the G*Power program (Universitat Düsseldorf)

Statistical analysis

Analyses were conducted on an intention-to-treat (ITT) basis; subgroup analysis were also reported for comparison. No data was missing for the primary outcome. Baseline continuous variables were presented as mean (SD) or median (IQR), and categorical variables as n (%). The between-groups differences were calculated using the change of each group and reported as mean or median differences with 95% confidence intervals (CI). We considered differences statistically significant if the 95% CI did not cross zero. Effect sizes of differences and ratios were reported with their 95% CI. The accepted Type 1 error in this study was 5%. Graphs were produced using GraphPad Prism 10.4.1 (GraphPad Software Inc., San Diego, California). Statistical analyses were performed using Jamovi version 2.3.26 (The Jamovi Project, Australia).