Femoral Triangle and Adductor Canal Blocks Versus Femoral Nerve Block for Total Knee Arthroplasty

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Study Protocol

Aim of the study: to evaluate and compare the femoral triangle and adductor canal blocks and the femoral nerve block regarding the, extent of motor blockade, postoperative analgesic efficacy, ability of early ambulation in patients following primary total knee arthroplasty.

Objectives:

1. To assess and compare the extent of motor blockade after the surgery between the femoral triangle and adductor canal blocks group and the femoral nerve block group after the primary total knee arthroplasty.
2. To compare postoperative pain control effects between the femoral triangle and adductor canal blocks group and the femoral nerve block group after the primary total knee arthroplasty.
3. To estimate the need for additional opioid analgesics and their adverse effects in the femoral triangle and adductor canal blocks and the femoral nerve block groups of patients after primary total knee arthroplasty.
4. To compare patients postoperative satisfaction rates between the femoral triangle and adductor canal blocks group and the femoral nerve block group after the primary total knee arthroplasty.

Design and Methods:

The prospective, double-blinded study includes American Society of Anesthesiologists (ASA) physical status I-III in preoperative assessment, aged 18-90 years, scheduled for primary total knee replacement surgery. Preoperatively patients will be blindly randomized into one of two groups: the femoral triangle and

adductor canal blocks group and the femoral nerve block group. Group assignment will be concealed by opaque envelopes that will be opened only after the patients enrollment. The anesthesiologist who will perform the block will be aware of the treatment, but the participant and outcomes assessor will be blinded to the group assignment. All blocks will be performed by the anesthesiologist under the ultrasound guidance. The femoral nerve block will be performed with 20 mL of 0.125% bupivacaine injection. The femoral triangle and adductor canal blocks will be performed together with injection of 10 mL of 0.125% bupivacaine for each block. During the perioperative period all patients will receive premedication of midazolam 2.5-5 mg and dexamethasone 4 mg. A slow fluid infusion of crystalloids with 1 g of tranexamic acid and 10 mg of ketamine will be started once as an intravenous cannula will be placed. Spinal anesthesia after identification of the subarachnoid space will be performed with 15 mg of levobupivacaine. After that, one of the peripheral nerve blocks will be performed. During surgery patients will be sedated with intravenous propofol. The local infiltration analgesia will be performed by the surgeon at the end of surgery with combination of 30 mL of 0.5% bupivacaine, 0.3 mL of 0.1% adrenaline and 90 mL of 0.9% sodium chloride. After the surgery patients will be transferred to the post-anesthesia care unit (PACU). After the surgery for analgesia NSAIDs will be available to both groups of patients. NSAIDs such as dexketoprofen 50 mg will be administered 2 times and acetaminophen 1 g will be administered 3 times per day. Opioids will also be available to patients as intramuscular boluses of pethidine 50 mg or morphine 10 mg without restriction and administered for moderate or severe pain. The extent of motor blockade will be evaluated at 3, 6, 24, 48 hours after surgery. Patients will be asked to flex the foot, to flex the knee and to lift up the straight leg. The possible leg motion at 3, 6, 24 and 48 hours postoperatively will be assessed with Bromage scale grades. Postoperative pain control efficacy will be assessed at 3, 6, 24 and 48 hours after surgery using visual analogue scale (VAS) from 0 to 10 (0 - no pain, 10 - worst imaginable pain) at rest, during active and passive 45 degree knee flexion. The requirement of additional analgesics and their adverse effects will be recorded.

Patients ability of early ambulation will be evaluated using Timed Up and Go (TUG) test at 24 and 48 hours after surgery. To do the TUG test, patients will have to sit down on the bed, get up from the bed, walk 3 meters forward, turn, walk back 3 meters to the bed and sit down. The time taken by a patient to perform this test will be calculated with a chronometer. After the conversation with each patient and assessment of postoperative pain control efficacy, extent of motor blockade, ability of early ambulation, the rate of patient satisfaction will be evaluated using a 10 point scale from 0 to 10 at 3, 6, 24, 48 hours after surgery. The rate of complications (if any), including falls, local anesthetic toxicity or neurological complications, will be recorded in both groups of patients. According to study protocol, both groups of patients will be compared in terms of the extent of motor blockade postoperative pain control, ability of early ambulation, need for additional opioid analgesics, satisfaction rates over the time of clinical recovery.

Statistical Analysis Plan

The age, gender, BMI, ASA status will be collected.

The variable for power calculation analysis is the difference in motor blockade between the groups of patients. The difference in motor blockade of 30% would be clinically significant. To detect differences for a power of 90% and a 2-tailed α error of 0.05, a sample size of 33 patients per group would be required. However, due to possible missing data, 80 patients will be included in the study.

The statistical analysis will be performed using SPSS (version 25.0 IBM). The Kolmogorov-Smirnov test will be used to assess the normality of data distribution. For normally distributed numerical variables the Student t test will be used to compare means. Categorical variables will be compared using the Chi-squared test. A p value < 0.05 will be chosen as statistically significant.