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Official Title: The Effect of Tourniquet Application on Analgesic Efficacy and Local Anesthetic Spread Pattern During Adductor Canal Block After Total Knee Arthroplasty: A Prospective Observational Study

• NCT Number: Not yet assigned •

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STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN

1. Background and Objectives :

The primary aim of this study is to evaluate whether a short-term tourniquet application during an Adductor Canal Block (ACB) modifies the distribution of local anesthetics. We hypothesize that the tourniquet acts as a mechanical barrier, preventing proximal spread toward the femoral nerve while facilitating distal redirection toward the popliteal region via the adductor hiatus to improve posterior knee analgesia.

2. Study Design:

This is a prospective, observational, comparative clinical study conducted at
Ankara Etlik Şehir Hastanesi Participants undergoing elective unilateral total knee arthroplasty are enrolled.

3. Intervention (The Tourniquet-Assisted ACB Technique):

Ultrasound Guidance: Procedures are performed using a GE LOGIQ™ system with a 6–15 MHz linear probe.

Procedure: Following surgery, patients receive an ACB. In the Study Group, a pneumatic tourniquet is applied to the proximal thigh (pressurized to 19–27 kPa). Initially, 20 mL of local anesthetic (0.25% Bupivacaine) is injected while the tourniquet is inflated to create a mechanical barrier. After 3–5 minutes, the tourniquet is released, and an additional 20 mL of the same solution is administered (Total: 40 mL).

The Control Group receives a standard single-injection ACB of 20 mL (0.25% Bupivacaine) without any tourniquet application. Real-time Monitoring: Local anesthetic spread is monitored dynamically via ultrasound to detect any proximal escape to the femoral nerve sheath.

4. Primary and Secondary Outcomes

Primary Outcome: Visual Analog Scale (VAS) scores at 3, 8, 12, and 24 hours postoperatively (both at rest and during movement).

Secondary Outcomes: Total opioid consumption within the first 24 hours (specifically Tramadol hydrochloride [Contramal]), presence of motor block (assessed by quadriceps muscle strength), and the dynamic pattern of local anesthetic spread (proximal vs. distal) monitored via ultrasound.

5. Statistical Analysis Plan (SAP) Sample Size: The sample size was determined to achieve a statistical power of 95% based on previous literature regarding VAS score reductions.

Data Analysis: Statistical analysis will be performed using SPSS software. Continuous variables will be expressed as mean ± standard deviation or median (interquartile range). Tests: Normality will be assessed using the Shapiro-Wilk test. Independent samples ttest or Mann-Whitney U test will be used

for group comparisons. Repeated measures ANOVA or Friedman test will be used for temporal pain score analysis. Significance: A p-value of < 0.05 will be considered statistically significant.