

Study Protocol and Statistical Analysis Plan

The impact of leg movement on the skin to adductor canal distance: a potential cause for catheter displacement?

NCT 03562559

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Objectives:

The primary goal of this study was to discover if there is significant change in the distance from the skin to the adductor canal with typical movements that happen after total knee arthroplasty. The secondary goals were to see absolute skin to adductor canal distance and if these changes in distance had any relation to the BMI and leg circumference.

Background Information:

Total knee arthroplasty (TKA) is increasingly common in North America due to growing obesity rates and an aging population¹. Effective pain control using a multimodal approach decreases narcotic use, enhances patient satisfaction and leads to quicker recovery². Regional anesthetic techniques such as the adductor canal block (ACB) have become a major component of the pain management strategy post TKA³⁻⁵.

Single injection ACB and continuous infusion via a catheter are both currently utilized with the latter conferring the theoretical benefit of prolonged analgesia⁶. The efficacy of catheter analgesia is predicated primarily on its proper placement and maintenance. Despite growing expertise and the use of ultrasound, catheter tip displacement has been reported as high as 26%⁷⁻⁸. In addition, recent trials did not show clear benefit of ACB catheters over single injections in terms of opioid consumption⁹ and pain scores¹⁰. This observational study seeks to investigate simple anatomic and mechanical factors that may contribute to catheter failure. Specifically, the trial examines the average SAC distance, and measures the relative distance changes as the leg is moved in various positions. It is hypothesized that the SAC distance changes with leg movement. If so, one may infer that repeated leg movements could gradually cause catheter tip migration while the catheter is secured to a fixed point on the skin.

Study Design and Methods:

After gaining ethics approval from the University of British Columbia (H17-02633) and registration with ClinicalTrials.gov (NCT 03562559) 40 patients undergoing total knee arthroplasty (TKA) were selected. Inclusion criteria were patients over the age of 18 undergoing TKA under spinal anesthetic that were capable of signing informed consent.

Demographic data was collected including height, weight, BMI, and sex.

Postoperatively, while still under the effects of the spinal anesthetic, measurements were made of the patient's surgical leg from the skin to the adductor canal using a HLF50X 15-6 MHz transducer on a SonoSite SII ultrasound machine (Fujifilm, Toronto, ON). The adductor canal was identified with the transducer in the transverse plane on the patient's thigh and the transducer footprint marked on the skin and the leg circumference was measured. This location is where one would normally perform the ACB at our institution with the superficial femoral artery (SFA) roughly abutting the trough of the sartorius muscle. The SFA in the adductor canal was used as a reference point for measurement. The distance from the skin to the most superficial and nearest point of the SFA was measured in the following positions: 1) neutral, 2)

neutral position with manual lateral displacement of the skin, 3) 30 degree external rotation, 4) straight leg raised to 30 degrees and 5) knee and hip flexed to 90 degrees. For each position the ultrasound image was saved and a measurement from the upper lateral corner of the image to the SFA was taken and recorded. A single operator (MT) performed all scanning and measurement, while a single assistant facilitated the various passive leg movements. The ultrasound transducer was kept in the premarked footprint and oriented perpendicular to the thigh to provide consistency.

Statistical Analysis Plan:

All data were tabulated using Microsoft Excel and difference in distance between the leg positions were calculated. The means of these distances were used to discover the 90% confidence interval in each of the leg positions relative to the neutral position. For the secondary objective the data were graphically tabulated relative to the patient's BMI and leg circumference. A line of best fit was then calculated using Excel.