

Clinical Comparison of Femoral Nerve versus Adductor Canal Block Following Anterior Cruciate Ligament Reconstruction: A Prospective, Randomized Clinical Study

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**Addendum: HSC-MH-14-0734 - Clinical Outcome Following Arthroscopic Knee Surgery
(COFAKS)**

“Clinical Comparison of Femoral Nerve versus Adductor Canal Block Following Anterior Cruciate Ligament Reconstruction: A Prospective, Randomized Clinical Study”

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- I. Purpose:** The purpose of this research addendum is to examine the potential differences between femoral nerve blockade (FNB) and adductor canal blockade (ACB) for pain control and quadriceps muscle activation for patients following anterior cruciate ligament (ACL) reconstruction. Patients enrolled within the “Clinical Outcomes Following Arthroscopic Knee Surgery - HSC-MH-14-0734” study will be recruited to participate, as the indicated procedures are currently being performed as “standard of care”. The study will be conducted at the University of Texas - Medical Center location in Houston, TX.

We intend to perform a matched prospective comparison of post-operative pain control and quadriceps muscle activation between blockade groups. The anesthesiology team, including Co-I (JW), currently administers both FNB and ACB in patients enrolled within the COFAKS study. We intend to use a matched control design to compare the effects of blockade on these outcome measures using the methods described below.

II. Specific Aims:

To compare femoral nerve versus adductor canal blockade for:

1. Pain control
2. Muscle strength

III. Hypothesis:

Adductor canal block will have no significant difference in regards to pain control compared to femoral nerve block. Patients receiving ACB will demonstrate fewer post-operative quadriceps strength deficits when compared to FNB.

IV. Background and Significance

Adequate pain control following anterior cruciate ligament reconstruction (ACL) often requires a regional nerve block. The femoral nerve block (FNB) has been traditionally employed. More recently, ultrasound application to regional nerve blocks allows for the

use of alternatives such as the adductor canal block following ACL reconstruction. In 2009, Manickam et al. were the first to describe the ultrasound guided adductor canal technique for the purposes of knee joint analgesia. Unlike other traditional techniques that seek to cause a sensory as well as a motor blockade, the adductor canal block attempts to spare the motor block of the neighboring distributions in an attempt to offer selective analgesia and strength preservation. Chisholm et al demonstrated the adductor canal block provides similar and adequate postoperative analgesia when compared to the FNB, following arthroscopic ACL reconstruction with patellar tendon autograft. Their study focused on analgesia and did not evaluate quadriceps function or impact on rehabilitation. Sharma et al drew the first association between femoral nerve blocks and increased fall risk due to muscle weakness in total knee arthroplasty population. A randomized, blinded study to compare quadriceps strength following adductor canal versus FNB was performed by Kwofie et al. They showed that compared with FNB, adductor canal block results in significant quadriceps motor sparing and significantly preserved balance. These studies focused on acute muscle weakness after regional anesthesia and its relation to safety. Quadriceps function is very important in rehabilitation of ACL reconstruction. Luo et al demonstrated long term deficits related to FNB. They demonstrated that patients treated with FNB after ACL reconstruction had significant isokinetic deficits in knee extension and flexion strength at 6 months when compared with patients who did not receive a nerve block. Patients without a block were 4 times more likely to meet criteria for clearance to return to sports at 6 months. In addition, Krych et al found significantly inferior quadriceps strength and function at 6 months in FNB group. Based on the available literature, we aim to compare femoral nerve versus adductor canal block in regards to pain control and muscle strength in ACL reconstruction patients until return to sport.

V. Methods

a. Study Design: Prospective Age-Matched Observational Cohort

b. Sample Population: Patients will be identified by participation in the Clinical Outcomes Following Arthroscopic Knee Surgery Study (COFAKS - HSC-MH-14-0734) will be provided verbal and written consent to participate if they meet the following criteria

i. **Inclusion Criteria:**

- Males & Females ages 16-30 yrs
- Undergoing ACL reconstruction by Co-Investigator (Walter Lowe)
- Receiving peri-operative FNB or ACB

ii. **Exclusion Criteria:**

- Not enrolled within the COFAKS study
- Receiving intrathecal nerve blockade or no blockade

c. Data Collection Timeline: 12/1/2015 to 12/31/2016

d. Surgical Blockade Methods: A majority of patients receiving anterior cruciate ligament surgery currently undergo a nerve blockade from the Co-Investigator

(WL) as standard of care. The purpose of this study was to compare post-operative patient outcomes (V.e.) for those receiving FNB to those receiving ACB.

- i. **Femoral Nerve Blockade (FNB):** Ultrasound guided FNB (30 ml of 0.2% ropivacaine with 100 mcg clonidine using a 22-gauge 40 mm ProBloc II insulated needle; Kimberly-Clark, Roswell, Georgia) below the inguinal ligament using a high-frequency linear ultrasound transducer (4–12 Hz; Mindray M7; Mindray North America, Mahwah, NJ) with stimulator confirmation.
 - ii. **Adductor Canal Blockade:** Ultrasound guided ACB (15 ml of 0.2% ropivacaine with 100 mcg clonidine using a 22-gauge 40 mm ProBloc II insulated needle; Kimberly-Clark, Roswell, Georgia) at the mid-thigh using a high-frequency linear ultrasound transducer (4–12 Hz; Mindray M7; Mindray North America, Mahwah, NJ).
 - iii.
- e. **Outcome Measures:** The outcome measures used in this study are considered standard of care, and are currently being collected as part of the daily practice patterns in post-operative rehabilitation.
- i. **Postoperative Pain control –**
 - Numeric Pain Rating Scale (NPRS): Measured acutely in PACU setting and with Pain control numeric scale at first physical therapy and postoperative physicians visit. See Appendix A.
 - Narcotics Use: Total costs for pharmaceutical utilization will also be tracked from the All-scripts EMR system utilizing the MRN linking variable for the parent protocol.
 - ii. **Quadriceps Muscle Activation**
 - Surface Electromyography (EMG): The surface EMG will be used at post-operative day 1, 7 and 14 to determine the muscle activation
 - Straight Leg Raise Test: *See section C.3. of the parent protocol - HSC-MH-14-0734.*

VI. Statistical Analysis:

Primary Analysis: Independent t-test and analysis of variance (ANOVA) models will be used to determine the differences between FNB and adductor canal block in regards to pain control and muscle strength.

Secondary Analysis: Pearson correlation models will be used to determine the relationships between patient demographic information and the outcome measures listed within the methods section - V.

VII. Power Analysis:

- a. Based on work by Hsu et al (AJSM 2013) and Kim et al (Anesth 2014) we intend to recruit 130 participants (65 FNB, 65 ACB) to sufficiently power this study. Kim et al (Anesth 2014) observed a moderate effect size of $d = .53$ for NPRS in patient following total knee arthroplasty. To achieve an acceptable power of $(1-\beta) = .80$ at an error rate of $\alpha = 0.5$ we will need to complete testing on 114 patients (Figure 1).

With a conservative drop-out estimate of 10% our total sample is estimated to be 130 participants.

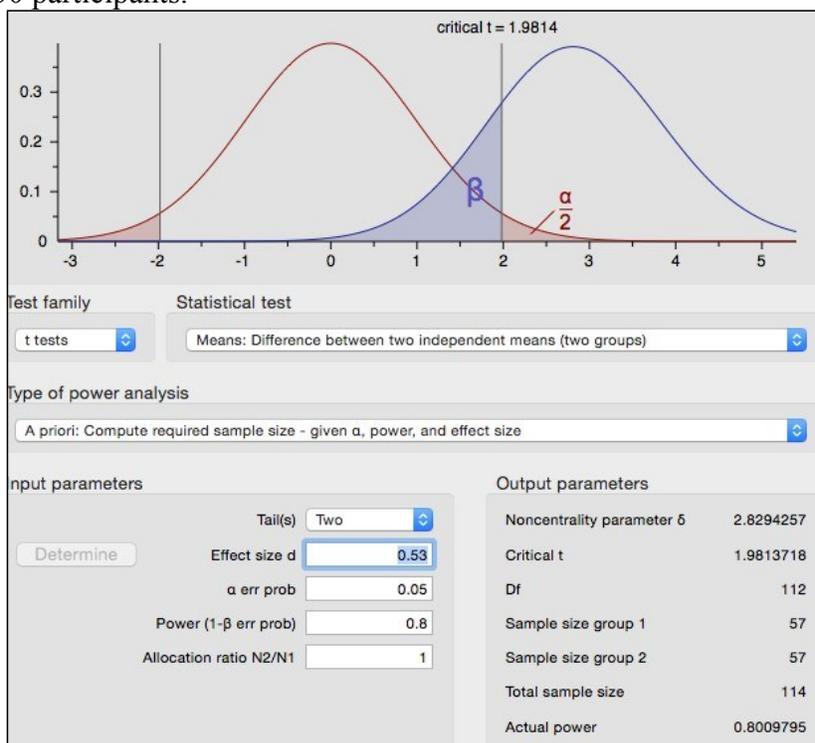


Figure 1. Power Analysis

VIII. Literature Cited / References

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Appendix A. Numeric Pain Rating Scale (NPRS)

