Pain Control for Anterior Cruciate Ligament Reconstruction; Two Prospective, Blinded, Randomized, Controlled Trials

Ajay Premkumar, MD, MPH Student, year 5
PI: John Xerogeanes, MD
Background – Pain After Surgery

- Pain delays recovery and rehab
- More pain → Less Patient Satisfaction
- Multi-modal approach to pain control
  - Nerve Blocks
  - Opioids
  - Local anesthetics
  - NSAIDs
  - Acetaminophen
Why Care about Pain after Surgery?

- Improved Healing
- Faster Mobilization
- Decreased risk of Pulmonary Emboli
- Shortened Hospital Stay
- Significant Reductions in Healthcare Costs ($$)
2 Studies

- Liposomal Bupivacaine vs. Bupivacaine HCl
  - “Long-acting” new local anesthetic vs. “short-acting” local anesthetic
  - Intra-operative injection

- Adductor Canal Block vs. Femoral Nerve Block
  - Two types of nerve blocks prior to surgery
Liposomal Bupivacaine for Pain Control for Anterior Cruciate Ligament Reconstruction;

A Prospective, Double-Blinded, Randomized, Positive-Controlled Trial

Ajay Premkumar, MD/MPH Student, Heather Samady, MD, Harris Slone, MD, Regina Hash, ATC, Spero Karas, MD, John Xerogeanes, MD
*All Liposomal Bupivacaine (®Exparel) was purchased through an unrestricted educational grant provided by Pacira Pharmaceuticals
Background

- Liposomal bupivacaine (Exparel)
  - 72 hour extended release of bupivacaine

- Promising vs. Placebo
  - Bunionectomy
  - Hemorrhoidectomy

- Benefit for ACL reconstruction?
To evaluate:

Liposomal Bupivacaine *vs.* 0.25% Bupivacaine HCl

For pain control following ACL reconstruction
Hypothesis

Analgesic benefits of liposomal bupivacaine:

- Less post-op pain
- Less post-op opioid use

compared to 0.25% bupivacaine HCl

*(Same Volume, Identical Administration)*
Materials & Methods

- Prospective, double-blinded, randomized, positive-controlled, single-center trial

**Inclusion Criteria:**
- Primary ACL reconstruction
- 18-50 years of age
- 2 surgeons
- QT or BPTB autograft

**Exclusion Criteria:**
- Revision procedures
- Other graft types
- Allergies to local anesthetics
- Chronic pain medication use
- Weight <50 kg
- History of Liver Disease
Materials & Methods

- 44 patients were prospectively enrolled
  
  Primary Outcomes:
  - Pain scores (0-10 Numeric Rating Scale)
  - Opioid use

  Secondary Outcomes:
  - Recovery room time & pain location
  - Time to first home opioid use & straight leg raise

- Paper journal or smartphone application for 1 week post-op
Materials & Methods

Randomized (n=44)

Allocation

Allocated to Control arm - 0.25% Bupivacaine HCl (n=22)
- Received QT autograft (n=16)
- Received BPTB autograft (n=6)

Allocated to Intervention arm - Liposomal Bupivacaine (n=22)
- Received QT autograft (n=16)
- Received BPTB autograft (n=6)

Follow-Up

Lost to follow-up (did not complete or return journal) (n=2)

Analysis

Analysed (n=20)
- Excluded from analysis (n=0)
- QT autograft (n=15)
- BPTB autograft (n=5)

Analysed (n=19)
- Excluded from analysis (hematoma formation and reoperation) (n=1)
- QT autograft (n=14)
- BPTB autograft (n=5)
Materials & Methods

- Consistent recovery room protocol
- Standardized home pain meds and instructions
- Data collected for 6 days after surgery
  - Pain reported at 12 hour intervals
  - # pills taken/day recorded each night
  - Pain location assessed via standardized image with examples
Summary of Results

- **NO** statistically significant differences
  - Post-op Pain
  - Opioid use
  - Pain location
  - Recovery room time
  - Mobility

between 2 study arms
Discussion

- No significant reduction in...
  - Pain
  - Opioid use

With liposomal bupivacaine vs. bupivacaine HCl

- FDA warning: prior studies questioned
- Cost significantly higher for liposomal bupivacaine
- Smartphone application a viable outcomes tool
Smartphone application

How fuse Works

Begin this journal when instructed by your physician

Keep track of all your medications

Record your pain levels night and day, along with any side effects you may be experiencing

Welcome to Day of Surgery!

Go to Med Tracker

Go to Pain Journal

Information

Frequently Asked Questions
How much pain do you have in your knee?  

0 4 10  
No Pain  Maximum

This is the front of the knee.
Strengths & Limitations

- **Strengths**
  - Study design
    - Prospective, randomized, double-blinded, positive-controlled clinical trial
    - 2 senior surgeons
    - Level 1 evidence
  - Strict inclusion/exclusion criteria
  - Standardized medication and exercise regimens

- **Limitations**
  - 12 hour pain question interval
  - Total mg of bupivacaine different in each arm
    - This should bias results in favor of liposomal bupivacaine
  - No placebo group
  - All patients received femoral block
  - Insufficient power for conclusions regarding graft type
We saw no effect on pain or pain medication use vs. generic alternative

Significantly increased cost

Difficult to justify use of liposomal bupivacaine over bupivacaine HCl for ACL reconstruction
Adductor Canal Block vs. Femoral Nerve Block for Pain Control for Anterior Cruciate Ligament Reconstruction; A Prospective, Single-Blinded, Randomized, Controlled Trial
Peripheral Nerve Blocks Commonly Used
- Better pain control than opioids alone

Gold Standard: Femoral Nerve Block (FNB)

Adductor Canal Block (ACB) Promising
- Less post-block motor weakness
- Sensory Block with Less Motor Blockade
- Similar Pain Control?

Benefit for ACL reconstruction compared to FNB?
To evaluate:

Adductor Canal Block (ACB) vs. Femoral Nerve Block (FNB)

For pain control for ACL reconstruction
Analgesic benefits of ACB:

- Less post-op pain
- Less post-op opioid use

compared to FNB

(Same Volume, Identical Administration prior to surgery)
Materials & Methods

- Prospective, single-blinded, randomized, controlled, single-center trial
- Broad inclusion Criteria

**Inclusion Criteria:**

- ACL reconstruction
- Any age
- 2 surgeons
- Any graft type
- Primary or Revision

**Exclusion Criteria:**

- Allergies to local anesthetics
- Chronic pain medication use
- Weight <50 kg
- History of Liver Disease
- History of Renal Disease
Both blocks:
- 20 cc 0.5% ropivacaine via 22-gauge 100mm stimuplex needle under ultrasound guidance by single attending anesthesiologist
- Prior to block, sterile skin prep and 1% lidocaine injection

Adductor Canal Block:
- Medial aspect mid-thigh
- Find Adductor Canal by visualizing femoral artery
  - Superiorly: sartorius
  - Laterally: vastus medialis
  - Medially: adductor longus

Femoral Nerve Block:
- Distal to inguinal ligament

Both Blocks Confirmed by Pinprick Sensation Testing & Quad weakness for FNB
80 patients were prospectively enrolled

- **Primary Outcomes:**
  - Pain scores (0-10 Numeric Rating Scale)
  - Opioid use

- **Secondary Outcomes:**
  - Recovery room time & pain location
  - Time to first home opioid use & straight leg raise
  - Hours of sleep per night
  - Patient satisfaction with pain control

- Paper journal or smartphone application for 1 week post-op
Materials & Methods

Enrollment

Assessed for eligibility (n=91)

Excluded (n=14)
- Declined to participate (n=11)
- Change of surgical procedure (n=3)

Randomized (n=77)

Allocation

Allocated to Group 1 (Femoral Nerve Block) (n=38)
- Received allocated intervention (n=38)
- Did not receive allocated intervention (n=0)

Allocated to Group 2 (Adductor Canal Block) (n=39)
- Received allocated intervention (n=39)
- Did not receive allocated intervention (n=0)

Follow-Up

Lost to follow-up (did not complete app) (n=7)

Lost to follow-up (did not complete app) (n=6)

Analysis

Analysed (n=31)
- Excluded from analysis (n=0)

Analysed (n=33)
- Excluded from analysis (n=0)
Materials & Methods

- Consistent recovery room protocol
- Standardized home pain meds and instructions
- Data collected for 6 days after surgery
  - Pain reported 3x/day
  - # pills taken/day recorded each night
  - Patient Satisfaction on POD 1 and POD 6
Summary of Results

- **Improved Patient Satisfaction after ACB**
  - 64% vs. 39% *Excellent* or *Good* on POD1  \( p=0.04 \)

- **Post-op Mobility better after ACB**
  - 16.4 hrs vs. 31.7 hrs  \( p=0.02 \)

- **NO** statistically significant differences
  - Post-op Pain
  - Opioid use
  - Recovery room time or pain
Discussion

- Improved POD1 Satisfaction with Pain Control (ACB)
- Improved post-op mobility (ACB)
- Similar Analgesia for FNB and ACB
  - Increased recovery room oxycodone (FNB)
    - Similar recovery room OME between arms
  - Increased pain during surgery night (ACB)
    - Similar hours of sleep on that and other nights
We saw

- similar analgesia
- improved mobility
- greater satisfaction with pain control

with Adductor Canal Blockade compared to Femoral Nerve Blockade
Future Directions

- Optimization of
  - Nerve Blocks
  - Local Anesthesia
  - Post-op Protocols
- Further studies in other settings are indicated
Thank You
References


