Liposomal Bupivacaine in Adductor Canal Blocks Before Total Knee Arthroplasty Leads to Improved Post-Operative Outcomes: A Randomized Controlled Trial

NCT: NCT04910165

Date: 4/01/2020

Purpose: To explore the effectiveness of Exparel (liposomal bupivacaine) in Adductor Canal Blocks for peri-operative pain control following a total knee arthroplasty (TKA) procedure: reduce opioid requirement use postoperatively, reduce pain scores postoperatively, provide earlier mobilization, and decrease length of hospital stay.

Methods: Our double blinded (patient and orthopaedic department) prospective randomized controlled study will collect 100 patients who receive an adductor canal block with Exparel and compare it with 100 patients who received and adductor block with ropivacaine. Each patient will be randomized using an online number generator. Only the anesthesiologist will be privy to which medicine was used in the block, with both the patient and the surgeon being blinded. Patients will either receive Exparel 20 ccs with 5 ccs of 0.5% bupivacaine in the adductor canal block and 20 ccs of 0.2% Ropivacaine in the iPACK block (Exparel group) or 25 ccs of 0.2% ropivacaine in the adductor canal block, and 20 ccs of 0.2% ropivacaine in the iPACK block (control group). These blocks will be placed in the pre-operative holding area under ultrasound guidance. Intraoperatively, patients will receive a spinal anesthetic utilizing 0.75% hyperbaric bupivacaine at the L3-4 or L4-5 levels and a propofol infusion for IV sedation. Patients will be seen in the PACU area, where pain scores and oral morphine equivalents (OME) are calculated. Patient will be seen on POD 1 to discuss expectations of pain control and goals for pain management (i.e. use of multimodal pain regimen and goals to decrease opioid use). Pain scores and OMEs will be calculated for POD 0-3. Progress notes in EPIC and patient interview will also disclose if patient had PT/mobilization early. We will finally review EPIC encounter for length of admission (date of admission to date of discharge), complication rates from the block, and readmission for pain.

Inclusion Criteria: Undergoing unilateral primary TKA for a diagnosis of knee osteoarthritis without additional concomitant procedures

Exclusion Criteria: Not undergoing a TKA after initially signing up for surgery, if they do not undergo spinal analgesia (due to medical contraindications or a failed attempt by the anesthesiologist), if the proper suspension or local anesthetic mixture is not utilized for the block due to physician error, or if they voluntarily drop out during the study period.

Risks and Benefits of Exparel:

Risks-side effects of Exparel include N/V, HA, and dizziness. As with any local anesthetic, more serious risks may include local anesthetic toxicity (neurologic and cardiac symptoms, cardiac arrest)
Benefits-Improved peri-operative pain control: we aim for a modest reduction of opioid use during the postop period (<60 oral morphine equivalents during first 2-3 days), decrease length of hospital stay (by 0.5-1 day), and reduction in pain scores

Study Visits:

Pre-op - Patient seen in Ortho office for initial consent to TKA and to fill out questionnaire (see attached). **Day of Surgery**- patient consented in the preoperative holding area with anesthesia, where blinding process occurs. Adductor canal block placed preoperatively.

After surgery- We will visit the patient in PACU to ask about pain scores and determine amount of opioid IV used in PACU. We will also visit the patient in POD 1 to discuss expectations of pain control. We will also look in EPIC to determine pain scores and OMEs during POD 0, 1, 2, and 3
Post-op visits 1,2, 3, and 4- Pain scores, WOMAC questionnaire scores, and opioid usage amounts collected

Sample Size Calculation:

1. LOS: 2.97 days (controls)-To detect a difference of .5 days (from 2.47 to 2.97, assuming the Exparel group has lower LOS), you need at least 41 patients per group if you assume a homogeneous population and 64 patients per group if you expect there to be greater heterogeneity.
2. NRS Pain score: 6 (controls)-To detect a difference of 1.41 points (from 4.59 to 6.00, assuming the Exparel group has lower pain), you need at least 22 patients per group if you assume a homogeneous population and 53 patients per group if you expect there to be greater heterogeneity
3. WOMAC: 21.5 point difference between pre op and post op score (expect a bigger difference in Exparel group)-To detect a difference of 15 points (21.5 for controls, 36.5 for Exparel patients), you need at least 11 patients per group if you assume a homogeneous population and 17 patients per group if you expect there to be greater heterogeneity.

Outcomes: WOMAC outcome scores (taken pre-operatively, and at 1 week post-operative visit, 2 week post-operative visit, 4 week post-operative visit, and 6 week post-operative visits), NRS Scores (taken on every hospital day and post-operative visit), Opioid Use (inpatient and outpatient), Hospital LOS, and hospital outcomes (complication, inpatient rehab, and readmission rates)

Analysis: Categorical and ordinal variables will be compared using Chi Squared and Fischer's Exact tests as appropriate, while numerical variables will be analyzed using Mann-Whitney-U tests. (IBM SPSS Version 23 Statistics for Windows, Armonk, NY: IBM Corp). For all analyses, $p < 0.05$ denotes statistical significance.