

University of Pennsylvania

# Protocol

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## **Comparison between single shot versus continuous infraclavicular brachial plexus block for postoperative analgesia after distal radius fracture, a prospective randomized open label study**

Pain control following fracture surgery is closely associated with overall patient satisfaction (1). Systemic analgesia (intravenous or oral) are not site specific and may be associated with undesirable side effects such as nausea, constipation, and pruritus. Peripheral blocks provide not only intraoperative anesthesia and pain control but also offer the advantage of lasting analgesic effect into the post-operative period. However, as these blocks wear off, some patients experience a high level of pain. This "rebound phenomenon" has been described and is considered by some authors as one of the shortcoming of single shot peripheral nerve blocks in multiple orthopedic surgical settings (2). Extension of the analgesic benefits of the peripheral nerve blocks can be achieved in the ambulatory settings using continuous perineural ambulatory catheters (3). Use of regional anesthesia for repair of distal radius fracture has been associated with improved pain scores and improved functional outcomes when compared to general anesthesia (4). The impact of extension of these benefits in the settings of distal radius fractures on patient satisfaction, the quality of pain management, quality of recovery, and functional outcome is not entirely known. This study aims to compare the effect of single shot infraclavicular brachial plexus blocks to continuous peripheral nerve blocks on pain scores after surgery.

### **Study Objectives:**

- 1- Measure visual analogue scores every 8 hours for 72 hours after surgery. Pain scores will be recorded by patients in a pain diary (see appendix)
- 2- Measure opioid requirements for the first 3 days after surgery
- 3- Measure patient satisfaction with their pain management.
- 4- Measure the quality of recovery (QOR) at 24 and 72 hours. using the QOR-9 questionnaire.( see appendix)
- 5- Measure the quality of sleep in the first two nights after surgery using a sleep questionnaire ( see appendix)
- 6- Functional outcomes will be assessed at 3 months follow up during the office visit or through administration of the disability assessment of shoulder and hand questionnaire, range of motion of the wrist and fingers will be recorded. (see appendix)

This study tests the hypothesis that patients receiving continuous ICB will have lower pain scores, will use less opioids, will sleep better the first two nights after surgery and will be more satisfied with their pain control regimen after surgery.

### **Methods:**

**Study design:** prospective, randomized, unblinded study with a parallel design and an allocation ratio of 1 to 1 for the treatment groups.

**Inclusion Criteria:** Patients scheduled for open reduction and internal fixation of a distal

radius fracture with American Society of Anesthesiologists (ASA) physical status I -III, mentally competent and able to give consent for enrollment in the study.

**Exclusion criteria:**

Allergy to local anesthetics. Impaired kidney functions and patient with coagulopathy will be also excluded. Patients opting to go under general anesthesia and those refusing the block will be excluded from the study. Chronic pain syndromes and patients with chronic opioid use defined as use of regular daily doses of systemic narcotics for the past 6 months prior to the surgery. BMI of 40 or more

**Recruitment:**

Patients will be identified from the surgical schedule the day before surgery and will be contacted by one of the study investigators to scan for eligibility for enrollment. Study aims and procedures will be explained to patients. Patients will be consented the morning of their surgery by one of the study investigator or the research coordinator.

25 patients will be enrolled in each study group with a total of 50 patients. Patients will be randomized to one of two study groups.

Group A will be named SS group, group B will be named the continuous infraclavicular block (CICB) group.

**Randomization:**

A computer generated randomization table will be used for patient allocation to one of the two study groups; The SS group, or the CICB group. Randomization will be done in blocks of 10 patients. Patients' assignments will be written in a sealed envelope that is only open after patient consent for the study.

The study will be unblinded. Patients, nurses in the recovery room, and the research coordinator will be aware of the nature of patient assignment. **Currently, most patients presenting with distal radius fracture at PPMC will receive a single shot brachial plexus block for intraoperative anesthesia. We offer the continuous block option to patients with history of chronic pain or previous adverse reactions to oral opioids. Also these practices may vary depending on surgeon and anesthesiologist preference. Access to analgesic medications will not be restricted by any means for both study groups because of the study procedures.**

**Statistical Analysis:** Statistical analyses will be preformed using STATA 13 statistical software, Dallas, TX. Demographic data will be analyzed using student's T test or fisher's exact test as appropriate. Repeated measurements (pain scores) will be analyzed by repeated measures ANOVA or ANOVA on ranks, with further paired comparisons at each time interval performed using the t-test or Mann-Whitney U-test as appropriate. Categorical data will be analyzed using X<sup>2</sup> analysis or Fisher's exact test where

applicable. Normally distributed data will be presented as means  $\pm$  SE of the mean (SEM), non normally distributed data are presented as medians  $\pm$  quartiles (interquartile range) and categorical data will be presented as raw data and as frequencies. The  $\alpha$  level for all analyses was set as  $P<0.05$ .

**Study procedures:**

In our institution we usually advocate for regional anesthesia and intravenous sedation for the repair of open fracture of the distal radius. Patients will be approached and consented for the study by one of the study staff.

Once consented their group assignment will be revealed to the anesthesiologist assigned to the room who will be performing the block

Patients will be monitored during block performance with standard ASA monitors. All patients will receive 2 L of oxygen via a nasal cannula. Sedatives will be titrated to effect. Midazolam 1-2 mg, and fentanyl 50-100 mcg will be used for sedation.

Block time out will be preformed according to standard operating procedure.

All blocks will be done under ultrasound guidance. Sonosite S nerve machine will be used with a low frequency curvilinear (C5) US probe with 2-5 MHZ frequency. Both single shot and continuous ICB will be performed according to the SOP in our department. Ultrasound survey of the deltopectoral groove below the clavicle will take place. The axillary artery and the three cords (posterior, medial and lateral) of the brachial plexus will be identified in short axis view deeper to the pectoralis minor muscle.

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For single shot blocks: A 4 inch 21 gauge single shot (B-Braun) needle will be introduced in-plane towards the posterior cord of the brachial plexus and 1-2 mL of dextrose 5% (D5%) bolus will be used to verify correct placement of the needle in the vicinity of the posterior cord and adequate spread pattern to both lateral and medial cord. 20 ml of Ropivacaine 0.5% will be injected through the needle with intermittent aspiration after each 5 ml bolus injection.

For the continuous block: A 4 gauge 18 inch touhy needle ( B –Bruan) will be introduced towards the posterior cord as above. When the needle tip and the pattern of spread is confirmed using D5% solution, a 21 gauge catheter will be introduced 2 cm beyond the needle tip under ultrasound visualization. The needle will be withdrawn over the catheter. Injection of a total of 20 ml of ropivacaine 0.5% ( in divided 5 ml boluses with intermittent aspiration) will take place through the catheter while observing the spread of local anesthetic under ultrasound. The catheter hub will be affixed to the upper lateral chest with sterile occlusive dressings and an anchoring device.

Block success will be defined as a change in cutaneous sensation to touch with an alcohol pad in the posterior, medial and lateral cord distribution over the forearm and the hand within 30min after injection. Subjects with successful catheter placement per protocol and nerve block onset will be retained in the study. Subjects with a failed catheter insertion or misplaced catheter indicated by a lack of sensory changes will have their catheter replaced or will be single shot blocked and withdrawn from the study.

Intraoperative sedation will consist of intermittent boluses of midazolam (1-2 mg), fentanyl (50-100 mcg) and propofol infusion, titrates to sedation and patient comfort (25-50 mcg/kg/min).

All patients will receive prophylaxis for postoperative nausea and vomiting (PONV) during surgery. The protocol for prophylaxis against PONV includes administration of 4 mg of dexamethasone after induction of anesthesia and 4 mg of ondansetron 20 minutes before recovery from anesthesia. Dexamethasone is withheld if the patient has poorly controlled diabetes mellitus (DM). Uncontrolled DM will be defined as random blood glucose above 250 mg/dl

**Protocol for postoperative analgesia:** At the conclusion of surgery, the catheters will be connected to a pump that will infuse local anesthetic. Ropivacaine 0.2% at a basal rate of 5 ml/hour and a patient administered on demand bolus of 5 ml with lock out interval every 60 minutes. In the PACU, intermittent boluses of hydromorphone will be used as needed. Postoperative analgesia will follow the current oral prescription protocol. Drugs that are used for postoperative analgesia include oxycodone/acetaminophen (5/325 mg) one to two tablets every four to 6 hours as needed by the patient with oxycodone 5-10 mg oxycodone oral tablets every 4 hours as needed for break through pain.

Patients will be followed up daily by the acute pain service resident as per our routine clinical practice for follow up for ambulatory perineural catheters. Patients will take out the catheter themselves at home as per protocol.

**Sample Size Calculation:** A power analysis done prior to enrollment showed that the number of patients needed to detect a 1-point change in pain score ( $p<0.05$  significance level) was thirty-eight patients. While a 1-point change in pain score may not be clinically significant, we wanted the study to have enough power to detect between a 1-2 point pain score difference. Assuming a dropout rate of 20%, we will enroll fifty patients. Sample size estimate followed a previously published study comparing single shot versus continuous popliteal block for pain control after ankle fracture (5).

#### **Study duration:**

We plan to begin enrollment in October 2015. The enrollment of all subjects is projected to be completed in October 2016 with data analysis to follow. The study is expected to be completed by January 2017. The length of participation for each subject will be three months total – 3 months as follow up data will be collected during the follow up office visits.

#### **Measurements:**

- 1- Visual analogue scores every 8 hours for 72 hours after surgery. Pain scores will be recorded by patients in a pain diary
- 2- Measure opioid requirements for the first 3 days after surgery
- 3- Measure patient satisfaction with their pain management.
- 4- Measure the quality of recovery at 24 and 72 hours
- 5- Measure the quality of sleep in the first two nights after surgery. sleep quality questionnaire is adapted from the insomnia severity index (6) and we added

another questions asking about the frequency of waking up at night because of pain after surgery (7, 8)

6- Functional outcomes will be assessed at 3 months follow up during the office visit or through administration of the quick disability assessment of shoulder and hand (DASH) questionnaire (9), range of motion of the wrist and fingers will be recorded.

1. Elkassabany N, Cai LF, Mehta S, Ahn J, Pieczynski L, Polomano RC, Picon S, Hogg R, Liu J. Does regional anesthesia improve the quality of postoperative pain management and the quality of recovery in patients undergoing operative repair of tibia and ankle fractures? *J Orthop Trauma*. 2015 Sep;29(9):404-9.
2. Williams BA, Bottegal MT, Kentor ML, Irrgang JJ, Williams JP. Rebound pain scores as a function of femoral nerve block duration after anterior cruciate ligament reconstruction: Retrospective analysis of a prospective, randomized clinical trial. *Reg Anesth Pain Med*. 2007 May-Jun;32(3):186-92.
3. Goldstein RY, Montero N, Jain SK, Egol KA, Tejwani NC. Efficacy of popliteal block in postoperative pain control after ankle fracture fixation: A prospective randomized study. *J Orthop Trauma*. 2012 Oct;26(10):557-61.
4. Egol KA, Soojian MG, Walsh M, Katz J, Rosenberg AD, Pakshima N. Regional anesthesia improves outcome after distal radius fracture fixation over general anesthesia. *J Orthop Trauma*. 2012 Sep;26(9):545-9.
5. Ding DY, Manoli A, Galos DK, Jain S, Tejwani NC. Continuous popliteal sciatic nerve block versus single injection nerve block for ankle fracture surgery: A prospective randomized comparative trial. *J Orthop Trauma*. 2015 Sep;29(9):393-8.
6. Morin C. insomnia severity index [Internet]. . Available from: [https://www.myhealth.va.gov/mhv-portal-web/anonymous.portal?\\_nfpb=true&\\_pageLabel=healthyLiving&contentPage=healthy\\_living/sleep\\_insomnia\\_index.htm](https://www.myhealth.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=healthyLiving&contentPage=healthy_living/sleep_insomnia_index.htm)
7. Ilfeld BM, Morey TE, Enneking FK. Continuous infraclavicular brachial plexus block for postoperative pain control at home: A randomized, double-blinded, placebo-controlled study. *Anesthesiology*. 2002 Jun;96(6):1297-304.
8. Ilfeld BM, Morey TE, Wang RD, Enneking FK. Continuous popliteal sciatic nerve block for postoperative pain control at home: A randomized, double-blinded, placebo-controlled study. *Anesthesiology*. 2002 Oct;97(4):959-65.
9. [Internet]. <http://www.iwh.on.ca/> cited 8/22/2015]. Available from: [http://dash.iwh.on.ca/system/files/quickdash\\_questionnaire\\_2010.pdf](http://dash.iwh.on.ca/system/files/quickdash_questionnaire_2010.pdf) English.