Comparison between single shot peripheral nerve block and continuous infusion via a On-Q Pump: a randomized prospective control trial

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Brief Summary

Peripheral nerve blocks have been well studied in the literature with generally good results for controlling post operative pain following orthopaedic surgery. Regional anesthesia has many benefits. It provides excellent intraoperative anesthesia and muscle relaxation as well as analgesia that continues into the post-operative period. These regional blocks are also effective in controlling pain in the immediate post-operative period. However, as the block wears off, patients begin experiencing increased pain. Compared to patients treated without regional blocks, these patients will often experience a "rebound pain"--pain occurring 12-24 hours after surgery that is subjectively worse than that in patients treated without regional blocks. Therefore, we propose to use a continuous infusion of anesthetic in order to provide sustained pain control post-operatively. Preoperatively, patients will be randomized into a single shot peripheral nerve block versus a continuous infusion of peripheral nerve block. Post-operatively, pain will be assessed using the Visual Analogue Scale (1-100) prior to being discharged from PACU. Time to discharge and amount of pain medication taken will be recorded. Patients will be contacted at certain time intervals postoperatively to assess their pain scale and pain medication intake. Patients will be seen for routine post-operative follow-up visits where they will be assessed for satisfaction, pain, residual neurological symptoms, and signs of infection.

Purpose

The purpose of this randomized prospective study will be to compare post-operative pain control after extremity fracture fixation surgery between patients who receive single shot versus continuous peripheral nerve blocks.

Scientific or Scholarly Rationale

Peripheral nerve blocks have been well studied in the literature with generally good results for controlling post operative pain following orthopaedic surgery [1-4]. Regional anesthesia has many benefits. It provides excellent intraoperative anesthesia and muscle relaxation as well as analgesia that continues into the post-operative period. Airway manipulations are avoided, post-operative nausea and vomiting are diminished, post-anesthesia care unit stay are shortened, and fewer nursing interventions in the post-anesthesia care unit are required[5-6].

Patients who have operative fixation of extremity fractures (ankle, wrist, forearm) are typically ambulatory patients. However, many become hospitalized overnight secondary to inadequate pain control, increasing hospital costs. Goldstein et al. showed that patients who underwent popliteal blocks after ankle fracture fixation demonstrated significantly better pain control immediately postoperatively[7]. The need for overnight hospitalization secondary to pain is decreased, as are nonsurgical operating room times.

Despite the success of regional anesthesia, a phenomenon known as “rebound pain” has been shown to occur as the original block wears off[7-9]. Patients with blocks will experience significantly increased pain compared to those without blocks approximately 12-24 hours after surgery. This can be controlled with early narcotic administration but can be a source of significant discomfort to a patient if not recognized

and treated in time. A few studies have shown that continuous infusions of various numbing agents are efficacious in prolonged pain control, even in the ambulatory setting[10-12]. Nevertheless, no studies have thus performed a randomized prospective control trial studying the efficacy of continuous infusion therapy on pain control following extremity fracture surgery.

Aims

1. To determine the effectiveness of continuously infused regional anesthetic for pain control in extremity fracture surgery
2. To determine the effect of rebound pain on patient satisfaction of surgery

Description of study and study procedure

Consent

All patients being treated with open reduction internal fixation for foot, ankle, tibia, elbow, forearm and wrist fractures at New York University Medical Center, NYU-Hospital for Joint Diseases will be asked to participate in this study. At the patients preoperative office visit, they will be asked to participate in the study and provided a copy of the consent form at that time which they can take home with them. All questions will be answered and they will be asked verbally if they will consent to being a part of the study. Patients will then have the opportunity to either sign the written consent forms or wait till the surgical date to think about the study and any additional questions they may have. At the time of surgery, patients will be consented for surgery. If the patient did not give written consent at the preoperative visit, they will be asked if they have any questions about the study. All questions will again be answered. They will then be asked verbally if they are willing to participate in the study, if they respond yes, then written consent will be obtained at that time.

Randomization

Patients will then be randomized (using an online randomizer, similar to a flip of a coin) to one of two anesthetic protocols: regional block with single dose of anesthetic versus regional block with continuous infusion using an OnQ pump. If for some reason, the anesthesiologist feels that a patient would benefit from one type of anesthesia over another, the patient will be removed from the study and given that type of anesthesia.

Intervention

Patients will be randomized to one of two anesthetic protocols: general anesthesia/sedation with a single shot, peripheral nerve block versus general anesthesia/sedation with a continuous, peripheral nerve block.

All anesthesia will be provided by an attending anesthesiologist with or without an anesthesiology resident/CRNA. Patients will have standard ASA monitors placed (pulse oximeter, blood pressure, EKG) and an intravenous line started. Sedation will be given using a combination of midazolam (1-4 mg) and fentanyl (25-100 mcg). Patients in both groups will receive an ultrasound-guided peripheral nerve block. The block will be either an infraclavicular brachial plexus block or a popliteal nerve block, depending on

the location of the fracture. The appropriate region will be prepped with a chlorohexidine solution on the appropriate surgical side and the appropriate site will be visualized under ultrasound. For the group receiving a single shot block, a 22 gauge, 3.5 inch needle will be used and 20cc of 2% lidocaine with 1:200,000 epinephrine + 20 cc of 0.5% bupivacaine with 1:300,000 epinephrine will be injected around the nerve after confirming negative aspiration every 5 cc. For those receiving a continuous infusion, a 17 gauge Tuohy needle will be used and 20cc of 2% lidocaine with epinephrine + 20 cc of 0.5% bupivacaine with 1:300,000 epinephrine will be injected around the nerve after confirming negative aspiration every 5cc. Once the injection is complete, an indwelling catheter will be placed with its tip location confirmed and then secured at the skin.

After placement of the regional block, general anesthesia/sedation will be administered and maintained at the discretion of the anesthesiologist. Induction of anesthesia will involve IV propofol (2mg/kg) and fentanyl (1-2mcg/kg). Neuromuscular blockade will be used at the discretion of the anesthesiologist and will be reversed appropriately. Anesthetic maintenance will involve inhalational agents, IV agents, air, and oxygen. Fentanyl will be the only intraoperative analgesic used and will be dosed as determined by the anesthesiologist.

After completion of the surgery, patients will be taken to the PACU where those with continuous catheters will have an OnQ pump attached to it. The patient will begin receiving a continuous infusion of 0.2% ropivacaine through the catheter at a rate of 8 cc/hr. The patient will be discharged home with the catheter for 48 hours. The study participant will self-discontinue the catheter in 2 days. This involves removing the tegaderm dressing and gently pulling the catheter out from under the skin. A bandage may then be applied. Germaine Cuff, our anesthesiology RN, will be available via phone to answer any questions study participants may have regarding discontinuation of the catheter. Breakthrough pain while in the PACU will be treated with IV fentanyl and PO Percocet as needed.

Postoperatively, all patients will be discharged home with a prescription for Percocet 5/325 with instructions to take 1-2 tabs every 4-6hrs as needed for pain.

Data collection

Location and type of surgical procedure, duration of procedure, and duration of intravenous sedation will also be recorded. Total time in the operating room will also be noted. Time admitted to PACU, time clinically ready for discharge, time actually discharge, PACU medications for nausea/vomiting and PACU meds for pain will all be recorded prior to discharge.

Post-operative pain will be assessed using the Visual Analogue Scale (0-100) prior to being discharged from PACU. Time to discharge and amount of pain medication taken in the PACU will be recorded.

Patients will be contacted 8 hours, 12 hours, 24 hours, 48 hours and 72hrs after surgery by the operative surgeon or research coordinator to assess their pain scale and pain medication intake. Patients will be seen for routine post-operative follow-up visits at two, six, twelve, twenty-four, and fifty-two weeks. At these times, patients will be assessed for pain, residual neurological symptoms, and signs of infection. Patients will also be asked if they were satisfied with their postoperative pain control. Total duration of study will be fifty-two weeks. Data collection documents will be distributed to the patients at time of surgery to assist in patient understanding.

Inclusion criteria

1. Patients at least 18 years old.
2. Male or Female
3. All racial and ethnic groups
4. Fractures and fracture/dislocations of the foot, ankle, tibia, fibula, elbow, forearm, wrist and hand
5. Patients who opt for surgical treatment of their fractures.
6. Patients who consent to be randomized.
7. Patients who are willing to follow-up for a minimum of 52 weeks.

Exclusion criteria

1. Patients younger than 18 years old.
2. Patients who are on chronic opioids
3. Patients who abuse opioids
4. Patients who are unwilling to follow-up for a minimum of 52 weeks.
5. Neurologic condition that could interfere with pain sensation

Characteristics of the Research Population

1. **Total number of subjects:** 100 subjects
2. **Gender:** Male or Female
3. **Racial and Ethnic Origins:** All are included

Study payments/cost:

Study participants will not incur any additional costs or payments as a result of this study. Any additional costs will be absorbed by the NYU Departments of Orthopaedics and Anesthesia

Potential Risks and Discomforts:

The research-related complications associated with regional block include, but are not limited to, intravascular injection, local anesthetic toxicity, hematoma formation around insertion site, infection around injection site, permanent or temporary nerve injury, and allergic reactions to the medication injected.

The research-related complications associated with the On-Q pump include, but are not limited to, site infection, superficial nerve injury, and local anesthetic toxicity. There may be additional risk of injury in the On-Q pump Group, if participants resume regular activities, prematurely, while free of pain.

There may be unknown risks/discomforts involved. Study staff will update all patients in a timely way on any new information that may affect the patients' health, welfare, or decision to remain in the study. If the patients have any questions or sustain any injury during the course of the research or experience any adverse reaction to one of the surgical treatments they will be informed during the process of obtaining informed consent that they should contact the Principal Investigator Dr. Nirmal Tejwani at the following telephone number 212-598-6599.

In addition, if there is any Adverse Event that occurs during the study, then the Principal Investigator will make the IRB aware of this. The Principal Investigator will submit a Reportable Events Form for all reportable information to the IRB within 5 working days from when the Principal Investigator learns of the event or new information.

Potential Benefits: The patients are not likely to receive any direct benefit from their participation in this study aside from possible increased pain relief after operative fixation of their fracture. However, the patients' participation may help the investigators better understand the best post-operative pain protocol for extremity fracture fixation. In addition, the patients' participation may help the investigators better understand if there is any prolonged benefit to with one post-operative treatment over the other, which could thereby give orthopaedic surgeons conclusive evidence of the best post-operative pain protocol for operative fractures about the forearm and wrist that could also translate into better patient satisfaction.

Data Monitoring Plan:

1. Types of data or events:
    a. Intravascular injection
    b. local anesthetic toxicity
    c. hematoma formation
    d. Infection
    e. Neurologic injury
    f. Allergic reaction
2. Responsibilities and roles for gathering, evaluating and monitoring the data:
    a. All data (including details about adverse/unexpected events) will be collected by the operative team or research coordinator at specific time points: 8hrs post-op, 24hr, 48hr, 72hrs, 2wks, 6wks, 12wks, 24wks and 52wks and reported to the research coordinator using standard templated data collection forms. All patients will be told to call Dr. Nirmal Tejwani at 212-598-6599 to report adverse reactions during the study.
    b. All data will be verified by the research team and coordinator for accuracy and compliance with the protocol at each time point as designated above.
3. Information about the monitoring entity:
    a. Principle investigator Dr. Nirmal Tejwani, Dr. Sudheer Jain, and Dr. David Ding comprise the monitoring entity.
4. Reporting Adverse events and Unanticipated problems to the monitoring entity:
    a. The Principal Investigator will submit a Reportable Events Form for all reportable information to the IRB within 5 working days from when the Principal Investigator learns of the event or new information.
5. Assessments:
    a. The Monitoring entity will review data monthly and assess the data for unanticipated problems involving risks to participants.
6. Criteria for Action:
    a. Specific triggers for action include any event that is deemed to be a risk to life or limb.
7. Procedure for communicating:
    a. The Principal Investigator will submit a Reportable Events Form for all reportable information to the IRB within 5 working days from when the Principal Investigator learns of the event or new information.

Data Storage and Confidentiality: All patients will be de-identified and given a code. Information linking the linkage codes to the participants' names, social security numbers and medical record numbers will be stored in a secure location separate from the medical information. Access to the information linking the linkage codes with participant identifiers shall be documented. The patient's informed consent will be obtained in one of the exam rooms in the private office.

Participant medical information will be stored electronically within a password protected spreadsheet available only to the PI, co-investigators, and research staff as necessary for data analysis. The names, social security numbers, and medical record numbers of the study participants will be deleted from their stored medical information and replaced with a linkage code. Access to participant medical information contained within the registry will be restricted.

Protection Against Risk: All procedures will be performed as outlined above. After the procedure pt will be contacted 6-8 hours after surgery and at 24 hours, 48 hours and 72hours after surgery by the operative surgeon or research coordinator to assess their pain scale and pain medication intake. Patients will be seen for routine post-operative follow-up visits at two, six, twelve, twenty-four, and fifty-two weeks. At these times, patients will be assessed for pain, residual neurological symptoms, and signs of infection, and starting at the six week time point, patient's functional status will be assessed using the Disability of the Arm, Shoulder and Hand (DASH) and SMFA scores, both are widely accepted and validated functional measures.

Method of Subject Identification and Recruitment: All patients seen in the outpatient office, who fit the inclusion criteria will be asked to participate in the study.

Subject/Representative Comprehension: None

Debriefing Procedures: All patients will have regular follow-up at which point, all questions regarding the study can be answered.

Documentation of Consent: A copy of the signed consent form will be securely kept for our records.

Statistical analysis plan:

A preoperative power analysis was performed. On a VAS scaled from 1-100, assuming a standard deviation of 20, the number needed to detect a 10 point changed in VAS was 38. Assuming a drop out rate of 20%, we will require 50 patients in each group to determine significance. The primary end points of the study for Visual Analog Score will be assess using two-group t-tests (Mann-Whitney U test where appropriate). Amount of pain medication utilized post operatively will be assessed using Student t-tests. Residual neurological symptoms and signs of infection will be reported as descriptive statistics. Descriptive statistics will be reported as means +/- SD for continuous variables and as frequencies and percentages for categorical variables.

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