Study Title:
Efficacy of Multimodal Periarticular Injections in Operatively Treated Ankle Fractures: A Randomized Controlled Trial

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Study Protocol:

Periarticular fractures (bone breaks extending into the joint surface) treated by orthopaedic surgeons are associated with significant pain in the post-operative period, often requiring high doses of opioid analgesics. In recent years, the high risk of misuse, abuse, and death associated with prescription opioid use has become increasingly evident. Although physicians are being advised to avoid administration of opioid prescriptions, alternative pain management options are limited. Currently, there is a need to investigate different pain management models in order to provide safe and effective pain relief during the post-operative period.

We aim to evaluate the effectiveness of peri-incisional multimodal injections as an alternative post-operative pain control method in orthopaedic trauma patients with operative ankle fractures. Approximately 200 patients will be randomized to either receive or not receive intra-operative injections in addition to standard opioid analgesic regimens. Post-operative pain management outcomes will be assessed and compared between the 2 study groups to determine effectiveness of the injections.

The proposed study will build upon related work to advance post-operative pain control regimens in orthopaedic surgery. Goals include the reduction of unnecessary patient suffering, reliance on opioids, and length of stay, while improving patient experience. These aims will be accomplished through the expansion of currently used multimodal periarticular injections from populations undergoing elective surgery to orthopaedic trauma patients with rotational ankle fractures.

The study design is a prospective, double-blinded, randomized controlled trial. Patients included in the study will be randomly assigned to one of two treatment groups: intra-operative multimodal periarticular injection or control (no injection). The peri-incisional injection will consist of ropivacaine, epinephrine, and morphine. All pharmacologic agents in the anesthetic cocktail are FDA approved and have been previously used in combination during other types of orthopaedic surgeries.

All patients included in the study will receive standard post-operative opioid analgesic regimens, administered ‘per needed’, regardless of their assigned treatment group per study protocol. ≥ 40 patients will be randomly assigned to each group. The patients enrolled in the investigation as well as health care professionals performing post-operative assessments and collecting data will be blinded to treatment allocation.

The feasibility of multimodal peri-incisional injections is supported by their current efficacy in populations undergoing elective orthopedic surgeries. These injections may be equally effective at reducing pain compared to regional anesthesia with continuous infusions, and single-shot nerve blocks.[7, 8]

We hypothesize that the injection cohort will have reduced pain scores, lower narcotic requirements, shorter length of stay, and be more likely to discharge to home following surgery.

We aim to evaluate the effectiveness of peri-incisional multimodal injections as an alternative post-operative pain control method in orthopaedic trauma patients with operative, closed, rotational ankle fractures. Patients undergoing surgical internal fixation of such fractures will be randomized to either receive or not receive intra-operative injections in addition to standard opioid analgesic regimens.

Control group will receive no injection and will receive IV and oral analgesics post-operatively.

Treatment group will receive injection during surgery into the periarticular space of ropivacaine, morphine, and epinephrine. They will also be provided with IV and oral analgesics post-operatively.

We will evaluate effectiveness of intra-operative injections by assessing inter-group differences in post-operative pain management outcomes, including: (1) subjective patient pain levels via visual analog scales in the immediate postoperative period; (2) quantity of opioid analgesics required prior to discharge; (3) post-operative length of stay; (4) discharge status (e.g. SNF, Rehab, Home).

We hypothesize that the injection cohort will have reduced pain scores, lower narcotic requirements, shorter length of stay, and be more likely to discharge to home following surgery.

Following consent, patients will be randomized by the research team using Microsoft Word (R) Random Number Generator.

Patients will be blinded as to whether they received the injection or not. This is possible as they will be unconscious in surgery during their procedure. While an inpatient, the patients will be notified that they may ask which arm of the study they are in during their 3 month followup visit***. Until then they will stay blinded.

They will then be treated with internal fixation of their fracture(s) as per standard of care.

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During this surgery, patients randomized to the peri-incisional injection cohort will receive a single, 25 mL intra-operative injection with medication following completion of fracture fixation and just prior to skin closure. The injection will be administered as such:
20 mL injected into the peri-incisional soft tissues in a circumferential fashion.
5mL injected into the ankle joint.

This will take approximately 2 minutes of total surgery time.

Following surgery, patients in the treatment and non-treatment groups will both be provided with the same intravenous (patient-controlled analgesia) and oral pain medications scheduled "per needed".

Following surgery, (and again at their followup visits up to 3 months following surgery) the research team will examine the patient medical record and record narcotic use by the patient during their hospital stay. They will also record clinical outcomes from the medical record. (Notably VAS score). At 3 months the patient will no longer be followed in the study. At this point, the patients requesting information on which treatment arm they were in can be told.

No follow-up after 3 months.