Regional Block for Postoperative Free Flap Care

Study Protocol & Statistical Analysis Plan

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Purpose:
The purpose of this protocol is to evaluate the safety and efficacy of regional anesthesia for head and neck patients undergoing microvascular free flap reconstruction.

Background:
The increasing rate of opioid related overdose mortality is well documented in the literature and approached 15 per 100,000 in 2017 (1, 2). Because of a growing epidemic in the US, the medical community is under scrutiny to curtail opioid prescription. However, this is weighed against surgical outcomes; importantly, postoperative pain has adverse effects on function, recovery and quality of life (3, 4, 5).

Regional anesthesia provides a non opioid based, pain control strategy. First, regional anesthesia decreases systemic adverse events including respiratory failure in abdominal surgery (6), decreases length of stay and improves rehabilitation in common orthopedic procedures such as total knee arthroplasty (7) and shoulder arthroplasty (8). Second, the physiologic benefits of regional anesthesia are compelling including augmented micro and macrocirculation, maintenance of body temperature and decreased systemic stress response through chemical sympathectomy (9, 10). Finally, regional anesthesia has been established as safe in the microvascular and anesthesia literature for pediatric (11), and adult patients (12, 13).

Participants (Screening and Selection)

a. How many participants are to be enrolled at UAB (if other sites relying on UAB IRB, list the number for each site)? **50**

b. Describe the characteristics of anticipated or planned participants (if multiple groups, repeat list for each group).

Sex: **All**

Race/Ethnicity: **All**

Age: **18+**

Health status: **All**

c. From what population(s) will the participants be derived? **Patients who have presented to Departments of Oral and Maxillofacial Surgery and Otolaryngology for evaluation and treatment of head and neck disorders requiring free flap reconstruction.**

Describe your ability to obtain access to the proposed population that will allow recruitment of the necessary number of participants: **The PI and sub-Is have practices specifically designated for treating head and neck disorders, with potential for enrollment. These patients will be identified from individuals treated by the investigators in their clinics.**

d. Describe the inclusion/exclusion criteria:

Inclusion criteria:

- **Age > 18**
- **Able to consent for themselves**
- **Undergoing a head and neck surgery at UAB with reconstruction using either a forearm free flap or a fibula free flap**

Exclusion criteria:

- **Age < 18**
- **Unable to consent for themselves**
- **Non-English speakers**
- **Non-resectable tumor**
- **Have a known opioid tolerance, or are on a home opioid regimen for a chronic condition. (Short-term opioid use for diagnostic procedures (i.e. biopsy) or new cancer diagnosis will be allowed).**
- **Patients with known hepatic failure, renal failure, or sulfa allergy, as determined by standard of care labs drawn within 30 days of enrollment**

e. If participants will comprise more than one group or stratification, describe each group (e.g., treatment/intervention, placebo, controls, sham treatment) **and** provide the number of participants anticipated in each group. **There will be two arms of the study:**

- **Control Group (to have 25 participants) will no regional anesthetic pain block intraoperatively. Participants will post-operatively receive acetaminophen 650 mg Q6hr, ibuprofen 400 mg Q6hr if GFR >60, oxycodone 5 mg Q6hr x 2 weeks for pain control. This will be our control group.**
- **Treatment Group (to have 25 participants) will receive a regional anesthetic pain block intraoperatively (US-guided ipsilateral sciatic nerve block for fibula free flap patients; US-guided infraclavicular brachial plexus nerve block and ropivacaine 0.2% for forearm free lap patients). Participants will post-operatively receive acetaminophen 650 mg Q6hr, ibuprofen 400 mg Q6hr if GFR >60, oxycodone 5 mg Q6hr x 2 weeks for pain control. This will be our control group**

Procedures:

Potential participants will be approached during their regularly-scheduled clinic visit about participation in the study. Only patients who have already been deemed appropriate surgical candidates prior to enrollment will be approached. If they agree to participate, they will sign an informed consent form. During this visit, we will collect demographic information, medical history, concomitant medications, vital signs, height, and weight.
Participants will be randomized to one of the two following groups:

- Control Group (to have 25 participants) will no regional anesthetic pain block intraoperatively. Participants will post-operatively receive acetaminophen 650 mg Q6hr, ibuprofen 400 mg Q6hr if GFR >60, oxycodone 5 mg Q6hr x 2 weeks for pain control. This will be our control group.
- Treatment Group (to have 25 participants) will receive a regional anesthetic pain block intraoperatively (US-guided ipsilateral sciatic nerve block for fibula free flap patients; US-guided infraclavicular brachial plexus nerve block and ropivacaine 0.2% for forearm free lap patients). Participants will post-operatively receive acetaminophen 650 mg

Q6hr, ibuprofen 400 mg Q6hr if GFR >60, oxycodone 5 mg Q6hr x 2 weeks for pain control. This will be our control group

Participants will have their scheduled functional endoscopic sinus surgery procedure. Participants randomized to the Treatment Group) will receive the appropriate regional anesthetic during the surgery. After surgery, participants will be given a pain diary to record their pain score on a scale of 1-10, and a place to record their use of opioids, as well as over-the-counter non-steroid anti-inflammatories such as acetaminophen and ibuprofen. Participants will record their scores and drug use daily for ten days post-surgery. At their first post-operative clinic visit, the diary will be reviewed, and their opioid use will also be evaluated by counting the pills left on their prescription.

Data points/variables to be collected during the study could include the following, to be ascertained from the medical record and/or patient report:

- Name
- Medical Record Number
- Age
- Gender
- Medications given by anesthesia intra- and post-operatively
- Post-operative pain medication used prior to and after discharge
- Post-operative complications
- Post-discharge/post-operative pain evaluation by patient diary

Benefits:

Benefits of this research include using a more effective and less risky pain regimen for head and neck surgery patients. We propose that the new pain regimen will result in better pain control and result in less opioid pain medication usage which would be safer for patients.

Risks:

There will be no additional clinical or surgical risks other than the normal risks for patients in this population undergoing this type of treatment.

There is a risk of randomization associated with this protocol, in that the treatment for the treatment group may prove less effective or have more side effects than the control group.

Though both the treatment group and the control group will receive be prescribed the exact same amount of opioid medication for use for post-operative surgical pain, there is a chance that the control group will use more of the medication than the treatment group for relief of their post-surgical pain.

Statistical Analysis Plan:

All statistical analyses will be completed using SPSS software, version 28 (SPSS Inc., Chicago, IL). For all tests, the statistical significance will be set at *P* values of <.05.

References:

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