STUDY TITLE: Evaluation of Bridge Device in Pain Management for Outpatient Rotator Cuff Surgery

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Proposal: Use of the “Bridge” device for pain management after ambulatory rotator cuff repair.

Investigators: Mariusz Ligocki (CA2), Steven Orebaugh, Henry Guo (CBY), Jacques Chelly, Amy Monroe, Mark Rodosky

Background:

Peripheral nerve blocks are effective for pain of shoulder surgery, including rotator cuff repair. However, single shot blocks are limited in duration, and their termination leads to rapid resumption of pain, sometimes termed "rebound" pain (1.). Catheters are more effective in providing long term pain control, but generally are removed by postoperative day three to avoid infection and due to pump reservoir limitations. In addition, they involve considerably more time, effort, personnel and cost, compared to single-shot blocks. Liposomal bupivacaine is a long-acting analgesic proposed to provide 72 hours of pain relief, but studies have been disappointing (2.). In a study conducted at our institution, Auricular stimulation, an alternative technique related to acupuncture, has been shown to reduce opioid consumption for the first three days after kidney donation surgery (3). A recent observational study including ambulatory shoulder surgery evaluated the "Bridge" device (manufactured by Masimo, previously FDA approved to reduce symptoms of opioid withdrawal) for postoperative pain control after application of single-shot nerve block (4.). The authors reported a markedly low opioid requirement among the patients, as well as very low postoperative pain scores. The device has proven simple to place, symptom-free, well-tolerated, and easy for patients to wear and remove at home. For these reasons, we would like to further explore the use of this non-invasive, alternative device for pain control among outpatient rotator cuff surgery patients.

The Bridge device, currently FDA approved for opioid use disorder, acts as a peripheral nerve stimulator/modulator. Nerves potentially affected by the electrodes placed on and around the ear include the auriculotemporal branch of the Mandibular Nerve, the posterior auricular branch of the Facial Nerve, the Glossopharyngeal Nerve, and the auricular branch of the Vagus Nerve, as well as the peripheral occipital and greater auricular nerves. This stimulation is believed to provide analgesic effects through influence on various neurotransmitters, including serotonin, norepinephrine and GABA, and has resulted in 56-75% reduction of opioid requirements in major abdominal surgery (4).

The device has an integrated 3 volt battery, with an impedance range of 1 to 10 kilo-ohms. It provides symmetrical, biphasic stimulation at a frequency of 0.125 Hz. Its package notes that it is contraindicated for patients with pacemakers, those with hemophilia (since the electrodes involve a micro-needle puncture), and psoriasis involving the ear. We would broaden this to include any patient with active anticoagulation, or any dermatologic condition involving the skin of the ear where the device would be placed.

Study Hypothesis: Use of the Bridge device will reduce opioid requirements (after resolution of block) by more than 33% on postoperative days 1 through 5.

Primary Outcome: Cumulative Oral Opioid Use (expressed as Oral Morphine Equivalents) on Postoperative days 1 through 5.

Secondary Outcomes: NRS pain scores recorded every four hours on postoperative days 0 to 4,
Oral opioid use on Individual Postoperative days 5 through 7
NRS pain scores recorded every 8 hours on postoperative days 4 to 7
Adverse effects related to opioids (nausea, dizziness, vomiting, itching)
Local adverse effects on ear related to use of bridge device (pain, etc)

Setting: UPMC West Mifflin Ambulatory Surgery Center, West Mifflin, PA. Specifically with use in ambulatory rotator cuff repair patients.

Subjects: We plan to enroll 15 patients in this observational, “proof of concept” study, in order to evaluate whether a 33% reduction in opioid use is possible over postoperative days 1 through five (after resolution of block), as compared to historical controls.

Procedures: Informed consent will be obtained, per IRB requirements. Standard anesthesia will be provided for rotator cuff repair for all patients. This includes single-shot bupivacaine interscalene nerve block with propofol sedation for the surgery itself, followed by application of the Bridge device in consented patients. Application of Bridge device occurs after surgery in recovery area. The ear is scrubbed with alcohol and electrodes placed in the required areas on or just in front of auricle. The device is then activated in the PACU. Patients will fill out a "pain diary" at home to record oral opioid use and pain scores as noted above, for first seven days after surgery. A study coordinator will call the patients on postoperative day 1, 3 and 7 to evaluate them. The device becomes inactive after 5 days and will be removed and discarded. At the end of 7 days, patients will fill out a Quality of Recovery survey, as well as a survey about the impact of the use of the device on their pain and recovery.

Endpoints: These include the primary and secondary outcomes noted above. At the end of five days, the device will be removed by the patient and discarded. Any patient who develops pain or skin irritation (or other adverse reaction) from the Bridge device will be advised to remove it and their participation will be stopped at that time.

Data Analysis: Descriptive statistics will be utilized, including comparison to historic controls. Mean pain values based on recorded NRS score for each postoperative day will be compared between groups. For the primary outcome, opioid ingestion over the entire interval of postoperative days 1 to 5 will be expressed as mean OME for each group, reported with 95% confidence interval. In pain scores, a difference of at least 1.7 on NRS scoring is considered to represent a meaningful clinical difference for shoulder surgery.

1. Abdallah FW Anesth Analg 2015;120:1114.
2. Hussain N. Anesthesiology 2021;134:147
3. Chelly JE. J Complement Integr Med 2021 doi:10.1515/jcim-2021-0208

4. Ilfeld BM Reg Anesth Pain Med 2022;47:581