

Title: The Effect of Auriculotherapy for Post-Operative Pain Management following Rotator Cuff Surgery:
A Randomized, Placebo-Controlled Study

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Cuff Surgery: A Randomized, Placebo-Controlled Study

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Introduction

The current opioid epidemic has led to a renewed interest in exploring non-pharmacological techniques to treat post-operative pain. An increasing number of patients are suffering from the adverse effects of opioid use following surgery, including post-operative nausea and vomiting, respiratory depression, immunosuppression, constipation, and most recently, addiction. In the United States, over \$600 billion is spent every year on opioid addiction, including \$79 billion related to opioid addiction following surgery. Despite many initiatives to decrease the use of opiates in the preoperative setting, opioids continue to be regularly prescribed before, during and after surgery. Although the risk of opioid addiction following surgery is recognized, the percentage of patients becoming addicted to opioids following surgery is not well understood. To date, there has been virtually no agreement regarding the duration and dosage that qualify for opioid dependence following surgery, nor that a clear estimation of the factors such as biological, psychosocial and socioeconomic that increase the risk of using opioids for extended periods of time after surgery.

The interscalene block is the gold standard for postoperative pain management following shoulder surgery. However, the duration of the block does not cover rehabilitation, and in most cases, patients are discharged from the hospital with an opioid prescription. Therefore, there is a growing need to investigate complementary pain-management methods that offer a non-pharmacological solution to managing post-operative pain. Auriculotherapy is such a technique that has been shown in previous studies to provide significant analgesia without the adverse effects of opioids or other pain-relieving medications. The objective of this trial is to investigate the efficacy of auriculotherapy in reducing post-operative narcotic consumption in participants undergoing rotator cuff surgery. Enrolled participants will be randomized to a control or interventional arm of the study, where they will either receive an active auriculotherapy treatment with nitrogen gas (intervention) or non-active auriculotherapy treatment without nitrogen gas (placebo).

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Background

Auriculotherapy is an ancient technique initially used to treat back pain and was rediscovered in the 1940s by French physician Dr. Paul Nogier, who postulated that the ear contains a complete representation of the body with the head down. The theory is that any pathological condition is associated with a corresponding modification of the ear point. The technique consists of invalidating the pathologic or dysfunctional ear point, which generates an impulse that is transmitted to the brain, where the brain tries to reset the ear point to homeostasis. The brain also tries to reset the corresponding point of the body to homeostasis.

Auriculotherapy is grounded in the concept that the ear can be considered a keyboard of the computer, with the brain being the hard drive, due to its embryologic origin and innervation. From an embryologic perspective, the conchae originate from the ectoderm, the lobe and ascending part of the helix, tragus and anti-tragus originated from the endoderm, Helix originated from the mesoderm. From the innervation perspective, specific parts of the ear are innervated by a specific branch of cranial nerves and plexus. These nerves carry impulses from the body to the ear, from the ear to the brain, and then back from brain to the ear. The fundamental principle of action of Auriculotherapy is based on a temporary and reversible invalidation of the somatotopic representation zones on the auricular cartography innervating the different section of the ear.

Auriculotherapy is neuro-physiologically based—a functional MRI study conducted in 2002 and duplicated in 2014 showed that the pain associated with the clamp of the thumb corresponded with illuminated sections of the brain. Over the last decades, several different cartography of the ear have been proposed—the most recent and scientifically-based cartography is using a segmentogram with a corpus collosum as the center of symmetry. Validation of this cartography has been obtained in studies using functional MRI.

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Specific Aims

1. This study will prospectively investigate the efficacy of auriculotherapy in reducing perioperative opioid consumption in participants undergoing rotator cuff surgery
3. To prospectively investigate role that auriculotherapy may have in reducing opioid consumption after discharge and facilitating functional recovery

Study Design

The study will be conducted as a prospective, randomized, placebo-controlled trial at the University of Pittsburgh Medical Center (UPMC) Shadyside Hospital and Montefiore hospitals. Institutional review board approval will be obtained before eligible patients are recruited and consented. Trial will be registered at www.clinicaltrials.gov before beginning recruitment.

Recruitment

Potential subjects will be recruited in the pre-operative area of Shadyside hospital on the day of their scheduled rotator-cuff surgery. Patients who agree to participate in the trial will sign an IRB approved Informed Consent Form.

Randomization Process

Participating patients will be randomized by computer generated random numbers to either the control or intervention group.

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Treatment Groups

Control Arm: Control group will receive an auriculotherapy placebo- this placebo involves using the auriculotherapy cryopuncture device **without** the compressed nitrogen gas to invalidate innervated points on the ear, plus the standard of care interscalene block and post-operative pain management protocol

Interventional Arm: Intervention group will receive actual auriculotherapy procedure, which involves using the auriculotherapy cryopuncture device **with** the nitrogen gas to invalidate innervated points on the ear, plus the standard of care interscalene block and post-operative pain management protocol

Inclusion Criteria

1. Subject is greater than 18 years of age
2. Subject is willing and able to provide informed consent
3. Subject is scheduled to undergo elective rotator cuff surgery
4. Subject has consented to an interscalene block

Exclusion Criteria

1. Opioid dependence
2. Any subject diagnosed with a chronic pain condition which daily opioid use is needed
3. Anatomical malformation, which in the investigator's opinion may interfere with the placement of the nerve block
4. Raynaud's disease diagnosis
5. Patient refusal

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Data Collection and Outcome Measures

Once patient has signed the Informed Consent to participate in this trial, demographic information and medical history will be collected from each participant on the day of surgery. Research staff will record this information from the medical chart. The Medical Outcomes Study Questionnaire 12-Item Short Form Health Survey (SF-12) will also be administered at this time to obtain baseline value.

Randomization will occur by assigning the participant a subject ID number, and this ID number will correspond to a treatment allocation based on a pre-designed randomization schema. This treatment allocation (intervention/control) will be contained in a sealed, opaque, envelope with the subject ID number that is designated on envelope. The master randomization list will be created and held by an independent data monitor who will both create and hold the master randomization list.

Once patient is randomized to a treatment group by research staff, Auriculotherapy will be performed using a cryopuncture device in the post-operative setting, either with nitrogen gas (intervention group), or an empty cryopuncture with no gas (control group). Dr. Chelly is formally certified in auriculotherapy (diploma attached). After proper disinfection of the designated ear, the treatment consists of the stimulation of 9 ear points on the ipsilateral ear. These points include: -Ω2 (the master point for the mesoderm), the shoulder point, 6 points involved with the pain pathway (the stellar ganglion, the sensory and motor C7 branches, the sensory master point (MSP), the reticular master point (RMP) and the point corresponding to the Thalamus).

Finally, the stimulation of the ACTH point completes the treatment. The total time required to complete auriculotherapy treatment is approximately 10 minutes

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The enrolled subject will also receive an interscalene block as per standard of care. The patient will receive standard of care treatment for surgery, post-operative pain management, and physical therapy.

After surgery, the subject will be assessed at time of hospital discharge to review how to complete the subject diary, administer pain satisfaction questionnaire (0-6) and obtain NRS pain at rest and with movement scores (0-10).

When the patient is discharged from the hospital, the subject will be asked to take home and complete a subject diary where they will record their total narcotic/pain medication consumption, pain satisfaction score (0-6), and NRS pain score (0-10), and adverse events daily for first 5 days post-discharge, and then at post op day 14 and once a month for three months (post op days 30, 60 and 90). The subject will be instructed to complete the diary just before bedtime on these days. The patient will be contacted via telephone on Day 5 post-operatively as a reminder to return their pain diary. On the post-operative Day 14, 30, 60 and 90 telephone calls, functional recovery will be measured using the Medical Outcomes Study Questionnaire 12-Item Short Form Health Survey (SF-12). The subject will also be asked to assess their overall patient satisfaction at the Day 90 call, on a scale of 0 (least satisfaction) to 10 (most satisfaction).

Analgesic efficacy in both groups will also be evaluated by the amount of total narcotic consumption (measured with oral morphine equivalent doses of analgesics used to provide pain relief). Secondary outcome measures will include total non-narcotic pain medication consumption for 5-days post-discharge, time to readiness for discharge from PACU, time to hospital discharge, readmission to the hospital because of pain-related issues, incidence of post operative complications, overall patient satisfaction, patient satisfaction relating to pain management and functional recovery. Functional recovery will be measured using the Medical Outcomes Study Questionnaire 12-Item Short Form Health Survey (SF-12).

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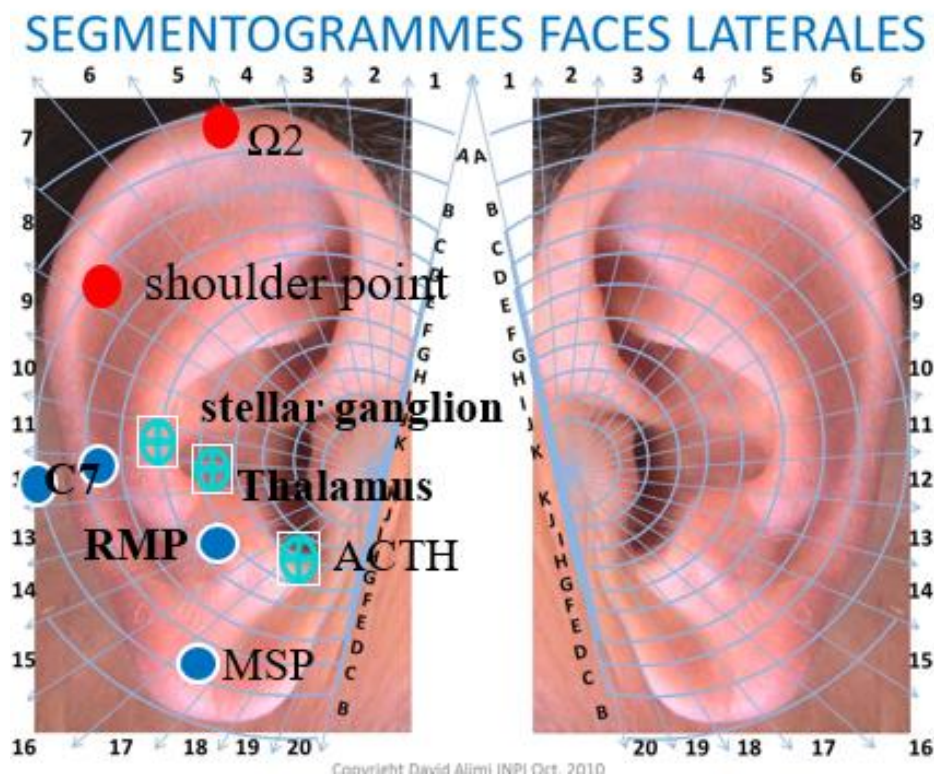
Auriculotherapy Technique

After proper disinfection of the designated ear, the treatment consists of the stimulation of 9 ear points on the ipsilateral ear.

These points include:

- $\Omega 2$ (the master point for the mesoderm), the shoulder point, 6 points involved with the pain pathway (the stellar ganglion, the sensory and motor C7 branches, the sensory master point (MSP), the reticular master point (RMP) and the point corresponding to the Thalamus).

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Statistical Analysis

A non-paired T-test will be performed to determine the significance of the difference between the 2 groups. P value less than 0.1 will be considered significant. Data for each outcome measure will be expressed as mean \pm standard deviation (SD). Confidence intervals and relative risks will be defined wherever appropriate.

Sample size power was based on a reduction of 60% of opioids during the 2 weeks following surgery and discharge. To allow for up to 10% dropout rate, 5 subjects have been added to each group to bring total to 50 subjects. Incidence of complications and other binary variables between the groups will be analyzed by Chi Square test or Fisher exact test.

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