Official Title: Nurse Initiated Auricular Acupressure for Post-operative Pain Management in Knee and Hip Arthroplasty Patients
NCT04044716
IRB-Approved Date: 10/19/20

Return Code for Ignite Grant: 4WHMKYRL
EIRB: 00057513
Study Title: Nurse initiated auricular acupressure for post-operative pain management in knee and hip arthroplasty patients
Principal Investigator, Co-investigator(s): Carolyn Huffman, WHNP, PhD; Remy Rene Coeytaux, MD

Sponsor or funding source: Departmental

Background, Rationale and Context

Postoperative pain management has become an area of concern over the last decade due to the opioid epidemic and concerns that the use of opioids as a primary pain management strategy in the post-operative period may promote misuse or abuse of opioids in the outpatient setting (Hah, Bateman, Ratliff, Curtin, and Sun, 2017; Alam, Gomes, Zheng, Mamdani, Juurlink & Bell, 2012). As of January 1, 2018, The Joint Commission requires hospitals to have non-pharmacologic modalities available for pain management in an effort to decrease the need for opioids. Acupuncture and acupressure have been used for centuries in the management of a variety of disorders including pain. A recent meta-analysis (Zhong et al., 2019) of 26 RCTs (all included studies were in China) favored the use of acupressure for pain management over usual care based on total effective rate (RR =1.25, [CI= 1.13, 1.37], p <.0001) and total analgesia use (RR=0.41, [CI= 0.24, 0.68] p = .0006). There were no serious adverse events reported in the 26 trials (N=1063 in treatment groups) and no withdrawals from the studies were reported due to adverse events. Unlike acupuncture, acupressure can be easily applied with training and is within the scope of practice for nurses, according to the North Carolina Board of Nursing (NCBON, 2013). Although acupressure has been used for centuries in traditional Chinese medicine, there are few studies assessing the use of nurse initiated acupressure in hospital settings as an adjuvant to post-operative pain management.

Battlefield acupuncture (BFA) was developed by Dr. Richard Niemtzow, a U.S. Air Force radiation oncologist. BFA utilizes 5 acupoints that are thought to be involved in central processing of pain. Dr. Niemtzow's protocol has been used in the United States military in the treatment of pain for over 15 years. In the last few years, the Veterans Administration in conjunction with the Department of Defense has expanded BFA training to providers within the VA system (Walker, et al., 2016). A cross sectional study of 753 patient BFA encounters (284 individual patients) within the West Haven VA Medical Center, found that patients receiving BFA showed on average a 2 point decrease in pain scores (measured on a 0-10 scale) with each BFA encounter (p < .001) (Federman et al., 2018). More recently, in an effort to increase access to non-pharmacological modalities for pain management, the VA has developed a **battlefield auricular *acupressure* (BAA) protocol**. The BAA protocol uses the same acupoints as the BFA protocol but instead of piercing the skin with needles to stimulate the acupoints, tiny beads or seeds are placed on the sites and stimulation of the sites is achieved when manual pressure is applied to the seed. The advantage of BAA is that since it does not require needles, patients may tolerate or be more open to its use, application of the seeds or beads is within the scope of practice of registered

The purpose of this pilot is to test the feasibility of nurse initiated post-operative battlefield auricular acupressure as an adjunct to medication for post-operative pain management.

Objectives

1. To determine if battlefield auricular acupressure applied in the immediate pre-operative period improves post-operative pain management related to:

a. total opioid intake over 5 days
b. aggregated mean pain score over 5 days
c. acceptability of auricular acupressure as pain management tool

2. To determine the feasibility of nurse initiated battlefield acupressure related to nurse time, cost and perceptions related to auricular acupressure and workflow.

Methods and Measures

Design

- Randomized controlled trial.

Setting

Davie Medical Center

Subjects selection criteria

- **Inclusion Criteria**
  Adults 18-80 admitted for knee or hip arthroplasty. Pre-surgery morphine equivalent < 50, ASA score $\leq$ 3
- **Exclusion Criteria**
  Participants with a history of skin disease (e.g., psoriasis) involving the ear, adhesive allergy, latex allergy, recent scar tissue on ear, or current abrasions or cuts on ear, history of delirium, or cognitive impairment. Some hearing aids may prevent proper placement of acupressure pads and thus, require exclusion. Since this is a feasibility pilot, only English speaking participants will be eligible.
- **Sample Size**
  Based on previous published literature, we estimate a total sample size of 48 -52 needed (24-26 each arm) to detect a 30% difference in pain scores or 25% reduction in analgesia. Recruitment target will be 30 in each arm (N=60) to allow for attrition. In order to identify the 60 subjects needed, we may need to screen as many as 120 because some people will not qualify to be included in the study.

Interventions and Interactions

Terms: AA = Auricular acupressure
Acupressure pad= hypoallergenic adhesive pad containing a 2 mm Vaccaria seeds (Earseeds®)
Acupoint = specific area of body where acupressure is applied.
BAA= Battlefield Auricular Acupressure

The three regional anesthesia nurses at Davie will be trained to deliver the intervention. All three nurses have been CITI trained and for this protocol will be referred to as auricular acupressure (AA) nurses. In addition to the three AA nurses, CTSI will provide study coordination.

- Training of the AA nurses for auricular acupressure will be done by the Wake Forest Center for Integrative Medicine (CIM) providers. Training will have both didactic and hands-on practice components: basic concepts of auricular acupressure, anatomy and physiology of the ear, assessment of ear anatomy, proper identification of therapeutic acupoints, proper cleaning of the ear, application of acupressure pads and activation, and patient education related to activation of the acupressure pads with manual pressure. Competency will be assessed both by assessment of knowledge (written assessment) and direct observation by CIM acupuncturist of the AA nurse's ability to correctly identify auricular acupressure points through visual inspection, proper application of acupressure pads and activation of the acupoints via manual pressure applied to the acupressure pads.

- Participants will be informed of the study at the time of their surgical consult with their physician or at their pre-operative appointment via flyers made available to the surgical clinics. Prior to the pre-assessment visit, study personnel will review the chart of patients who express interest in the study to confirm eligibility. Informed consent will be obtained at the pre-operative assessment visit by study personnel and the participant questionnaire will be reviewed with instructions on the day of surgery, the AA nurse will confirm consent for participation. Random assignment will be generated by REDCap and emailed to the AA nurse by the study coordinator. If participant is assigned to treatment, the acupressure pads will be placed in the pre-operative holding room. The participant's designee will be given the study questionnaire packet as well as instructions for completing.
- AA nurses will record time from the moment they enter participant's room in holding room for the purposes of placing acupressure pads and activating each pad until they exit room. AA nurses will make notation if recorded time includes activity unrelated to placement of acupressure pads. After placement of acupressure pads, AA nurse will enter procedure note in WakeOne and complete the REDCap nurse questionnaire.

- **Treatment Group**: The AA nurses will place the acupressure pads on the participant pre-operatively while the participant is in the PACU using the following BAA protocol:

    - Before acupressure pad placement, pain assessment will be performed and recorded in the study chart by the AA nurses. AA nurse will also ensure that a responsible family member is in the pre-operative holding room with participant to listen to instructions.
    - Acupressure pads will be placed prior to any amnesic or pain medication.
    - AA nurse will have participant don surgical cap, being careful to keep all hair under the cap.
    - If the ear contains lesions, skin breakdown, or show signs of irritation, the acupressure pads will not be placed and this will be noted in the study record.
    - A total of 10 adhesive acupressure pads will be placed, 5 acupressure pads per ear. The pads will be placed bilaterally on the following 5 auricular sites: 1) Cyngulate gyrus, 2) Thalamus, 3) Omega 2 4) Point Zero, and 5) Shen Men. These sites were selected based on the WV's Battlefield Auricular Acupressure Protocol for acute and chronic pain. This is the protocol the Veterans Administration uses for acupressure therapy for acute and chronic pain management and is taught to both nurses and physicians. Each ear will be cleansed with alcohol, beginning at the base of the ear (lobule) to the apex. The acupoints will be visually located and marked with a sterile surgical marker. The pads will be placed by visual identification of the preselected acupoints as per BAA protocol. The pads will be placed on the on the identified site by hand or with the assistance tweezers, with the seed portion of the pad aligning with the identified acupoint. To secure the pad, gentle but firm pressure will be applied to the pad, making sure that pressure is applied to the entire pad.
    - After placement, the study nurse will apply moderate pressure to each acupressure pad for 30 seconds (total time 2.5 minutes per ear). Both right and left ear site will be stimulated at the same time with pressure in the following order: 1) Cyngulate gyrus, 2) Thalamus, 3) Omega 2, 4) Point Zero, and 5) Shen Men Participants will tell the AA nurse when they feel a tingling sensation in the ear or feel moderate tenderness or pressure as confirmation that moderate pressure is being applied.

- The AA nurse will document in WakeOne acupressure pad placement and activation.
- Once participant is transferred to the floor, the AA nurse will review with participant and family how and when to activate each pad and give participant or designee a picture of a right and left ear with the acupressure pads in place with pads labeled 1-5. Participants will be reminded to gently press on each pad for 30 seconds three times a day to activate and to do this three times a day for a total of 5 days (roughly every 6-8 hours, while awake during the day). The provided picture will be used by the participant to account for any missing pads on the participant questionnaire. If the participant requests, the AA nurse will take a picture with the participant's smartphone of the participant's ears with the pads in place. The study questionnaire will also direct participants to apply moderate pressure using thumb and forefinger to each pad for 30 seconds each three times a day.
- If acupressure pads fall off while the participant is still in the hospital, the participant and/or nursing staff will be instructed to call the AA nurse on call for replacement of the pads prior to discharge.
- Participants may stimulate both ear sites at the same time beginning with site 1 and ending with site 5. Studies have placed acupressure pads for 3-8 days depending on study outcomes (He et al., 2013; Yeh et al., 2014), the pads will be placed for a total of 5 days based on manufacturer's recommendation and the BAA protocol (See example of Earseeds instruction brochure). On the day of surgery, the participant will be informed to apply pressure one to 2 more times that day, depending upon the time the acupressure pads were placed. Participants will be informed that if any acupressure pads fall off while home, they are not to be replaced, but to record on the study questionnaire (see participant questionnaire). Staff nurses will remind participants to complete their questionnaires and to call the AA nurses with any questions related to the acupressure pads or the study.
- At time of discharge, the study personnel will ensure that the participant has participant questionnaire and the addressed and stamped envelope. Instructions for activation of the acupressure pads and questionnaire completion will be reviewed. Participants will be informed that they will either receive a phone call or text reminder twice daily to complete the questionnaire and to activate their pads 3 times per day. Participant is to continue to apply pressure to remaining pads until the end of the study.
- On post-operative day 4, the study personnel will call the patient and instruct them to remove the acupressure pads by gently pulling on the edges of the pad and lifting off with their fingers or using tweezers to loosen the pad if needed. Participants will be reminded to mail questionnaire in the provided postage paid envelope, if they have not done so already

- **Control Group:** The AA nurse will give participants in the control group the study questionnaire once they arrive to the floor and remind participant and family to complete the questionnaire as indicated. At time of discharge, study personnel will ensure that participant has study questionnaire and the addressed and postage paid envelope. Participants will be informed that they will either receive twice daily phone calls or text messages to complete the questionnaire. On postoperative day 4, study personnel will call and remind participate to mail questionnaire in the provided postage-paid envelope.

- Contact information will be obtained at time of study enrollment/consent in order to remind participants daily to complete study document. The reminders will be via telephone call by study personnel and/or via text messaging depending on participant preference. Participants may also be contacted to complete the final questionnaire over the phone if the document if this section is incomplete when received by the study team.

Ambulatory Appointment	**Preoperative Assessment**	**Day of Surgery**	**Recovery Rm**	**PO-0**	**PO-1**	**PO-2**	**PO-3**	**PO-4**
Study flyer	Study flyer	R	O_1 X	O_2 X	O_3 X	O_4 X	O_5 X	O_6 X
	Informed Consent	Informed Consent	O_1	O_2	O_3	O_4	O_5	O_6

Note: O= Observation; R = Randomization, X = Acupressure pellet placement and/or activation with manual pressure.

Outcome Measure(s)

1) Pain: Both inpatient and outpatient pain scores will be measured using the VAS as documented on the participant study questionnaire.
    a. am pain score on rising aggregated over 4 days (post-op day 1 –post-op day 4)
    b. pm (worse pain throughout the day) pain score aggregated over 5 days (post-op day 0 – post-op day 4)
    c. trajectory of am and pm pain scores
2) Inpatient opioid pain medication will be collected via the MAR in WakeOne. Outpatient usage will be self-reported in study questionnaire. Inpatient and outpatient total opioid use will be converted to total Morphine equivalent.
    a. Total morphine equivalent aggregated over day 0-4
    b. Trajectory of morphine equivalent from day 0 - 4
3) Overall participant satisfaction will be measured on post-op day 4 via participant questionnaire.
4) Nurse time will be measured in minutes from time AA nurse enters room to place acupressure pads to when AA nurse exits room. Qualitative questions will be used to assess overall feasibility of nurse initiated auricular acupressure.

Outcome	Measure	Baseline	Post-op Day 1-2	Post-op days 1-4
Pain	Visual Analogue	**X**		**X**
Medication Inpatient	WakeOne MAR Participant Questionnaire		**X**	**X**
Medication Use Outpatient	Participant Questionnaire			**X**
Pellet Retention Days	Participant Questionnaire		**X**	**X**
Pain Management satisfaction	Participant Questionnaire			**X**
Nurse Time	Questionnaire		**X**	
Nurse Feasibility	Questionnaire		**X**	

Analytical Plan

Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Multilevel modeling will be used to determine difference in pain and morphine equivalents over time.

Human Subjects Protection

Subject Recruitment Methods

Several strategies will be implemented to assist with recruitment. Participants may be identified by screening provider schedules. They will be recruited by mailed recruitment letter, myWakeHealth message, telephone, and/or in person when presenting for their surgical consent or pre-operative assessment visit (as allowed by institutional and government policies).
Informational flyers describing the study will be disseminated to the orthopedic clinics at Davie Medical Center. Recruitment will also be done through the orthopedic clinic at the time of a patient's pre-operative assessment visit in one of three ways: 1) patients will be given an informational flyer and instructed to call study phone line if interested in participating, 2) they may ask to receive a call from the study team, or 3) they may meet directly with a study team member the day of their pre-operative assessment visit if a study team member is available.
Study personnel will review eligibility questionnaire with participant (confirm age, date of pre-assessment appointment, date of surgery, type of surgery, presence of pacemaker or other electrical device, hearing aid use, skin disorder or allergies, current medications). If eligible based on phone or in person screen, study personnel will do second stage eligibility screen via WakeOne chart review to calculate current morphine equivalent, medical history for delirium, ASA status, and cognitive impairment or delirium. If eligible, participant will be consented by study personnel at their pre-assessment anesthesia visit or on the day of surgery. The study personnel will maintain a record of eligible study participants. This list will include name, MRN, surgery type, pre-assessment appointment, and surgery date will be kept in a secure file on a secure computer. The file of eligible participants will be destroyed at the end of recruitment.

Informed Consent

Signed informed consent will be obtained from each subject. The study personnel will obtain informed consent at the time of the pre-operative assessment or on the day of surgery. The AA nurse will be contacted to come and speak with patient to answer any questions prior to signing consent. During COVID-19, we plan to obtain consent remotely in cases where the study team is not able to have face to face contact with the participant. In order to obtain legally effective consent, the investigator or member of the study team will provide two copies of the approved consent form for documentation. After received, the study team member will speak with the participant, presenting the elements of consent, the content of the study, and answer any questions. At the end of the discussion, the study team member will advise the participant to sign and date one form and return the signed consent form to the study team. The study team will clarify that the second consent form should be kept by the participant for documentation. Upon receipt of the signed form, the study team member will sign and date with the current date, and add a note detailing the date discrepancy. No study procedures will begin until the IRB approved method of obtaining consent is completed. Participants will be reminded that if the signed consent form is not received prior to the surgery and if there is not a study team member available to consent prior to the surgery, they will not be able to participate in the study.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the stored data collection forms. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection, subject identifying information will be destroyed three years after closure of the study, and files will be erased. Each study participant will be assigned a unique identifier that will be linked to their name. The participant study questionnaire will contain the patient's name and after collection of the study questionnaire from the patient, the study coordinator will replace the name on the study questionnaire with the participant's unique identifier and data will be transferred to the study data base with data validation producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal and co- investigator will be responsible for the overall monitoring of the data and safety of study participants. They will be assisted by other members of the study staff. Although no serious safety events have been reported in the literature related to auricular acupressure, participants will be asked to report any events to study personnel. Participants will be instructed to monitor and report any concerns related to acupressure pads to the AA nurse on-call and these will be escalated to the PI and then to the Co-investigator for evaluation, if needed. The co-investigator or a licensed acupuncture provider at the Center for Integrative Medicine will serve as consulting physician/acupuncturist for any adverse event that is determined to be potentially related to the study, including physical examination and treatment if necessary.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

1. Alam, A., Gomes, T, Zheng, H., Mandani, M. M., Juurlink, D. N., & Bell, C. M. (2012). Long-term analgesic use after low-risk surgery: A retrospective cohort study. Journal of the American Medical Association, 172(5), 425-430.
2. Hah, J.M., Bateman, B.T., Ratliff, J., Curtin, C., & Sun, E. (2017). Chronic opioid use after surgery: Implications for perioperative management in the face of the opioid epidemic. *Anesthesia & Analgesia, 125*(5), 1733-1740.
3. He, B. J., Tong, P. J., Li, J., Jing, H. T., & Yaom X. M. (2013). Auricular acupressure for analgesia in peri-operative period of total knee arthroplasty, *Pain Medicine, 14*, 1608-1613.
4. North Carolina Board of Nursing (2013). Complimentary Therapies: Position statement for RN and LPN practice.
5. The Joint Commission (2017, August 29). Pain assessment and management standards for hospitals. *R^3 Report,* 11.
6. Yeh, C.H., Chien, L-C, Huang, L. C., Suen, L. (2014). Auricular point acupressure for chronic pain: A feasibility study of 4-week treatment protocol. *Holistic Nursing Practice, 28*(3), 184-194.
7. Zhong, Q., Wang, D., Bai, Y-M., Du, S., Song, Y-L., & Zhu, J. (2019). Effectiveness of auricular acupressure for acute postoperative pain after surgery: A systematic review and meta-analysis, *Chinese Journal of Integrative Medicine, 25*(3), 225-232.

Appendix

1. Participant Study Questionnaire
2. Nurse questionnaire
3. Consent form
4. Acupressure Sites
5. Davie Medical Center Total Joint Program Inclusion Criteria